AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

THE AUTISM EPIDEMIC—IS THE NIH AND CDC RESPONSE ADEQUATE?

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

APRIL 18, 2002

Serial No. 107–74

Printed for the use of the Committee on Government Reform

Available via the World Wide Web: http://www.gpo.gov/congress/house
http://www.house.gov/reform

U.S. GOVERNMENT PRINTING OFFICE
80–356 PDF WASHINGTON : 2002

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON GOVERNMENT REFORM

DAN BURTON, Indiana, *Chairman*

BENJAMIN A. GILMAN, New York
CONSTANCE A. MORELLA, Maryland
CHRISTOPHER SHAYS, Connecticut
ILEANA ROS-LEHTINEN, Florida
JOHN M. McHUGH, New York
STEPHEN HORN, California
JOHN L. MICA, Florida
THOMAS M. DAVIS, Virginia
MARK E. SOUDER, Indiana
STEVEN C. LaTOURETTE, Ohio
BOB BARR, Georgia
DAN MILLER, Florida
DOUG OSE, California
RON LEWIS, Kentucky
JO ANN DAVIS, Virginia
TODD RUSSELL PLATTS, Pennsylvania
DAVE WELDON, Florida
CHRIS CANNON, Utah
ADAM H. PUTNAM, Florida
C.L. "BUTCH" OTTER, Idaho
EDWARD L. SCHROCK, Virginia
JOHN J. DUNCAN, JR., Tennessee
——— ———

HENRY A. WAXMAN, California
TOM LANTOS, California
MAJOR R. OWENS, New York
EDOLPHUS TOWNS, New York
PAUL E. KANJORSKI, Pennsylvania
PATSY T. MINK, Hawaii
CAROLYN B. MALONEY, New York
ELEANOR HOLMES NORTON, Washington, DC
ELIJAH E. CUMMINGS, Maryland
DENNIS J. KUCINICH, Ohio
ROD R. BLAGOJEVICH, Illinois
DANNY K. DAVIS, Illinois
JOHN F. TIERNEY, Massachusetts
JIM TURNER, Texas
THOMAS H. ALLEN, Maine
JANICE D. SCHAKOWSKY, Illinois
WM. LACY CLAY, Missouri
DIANE E. WATSON, California
STEPHEN F. LYNCH, Massachusetts
———
BERNARD SANDERS, Vermont (Independent)

KEVIN BINGER, *Staff Director*
DANIEL R. MOLL, *Deputy Staff Director*
JAMES C. WILSON, *Chief Counsel*
ROBERT A. BRIGGS, *Chief Clerk*
PHIL SCHILIRO, *Minority Staff Director*

CONTENTS

	Page
Hearing held on April 18, 2002	1
Statement of:	
Boyle, Coleen, Associate Director for Science and Public Health, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, accompanied by Melinda Wharton, Director, Epidemiology and Surveillance Division, National Immunization Program, Centers for Disease Control and Prevention; Stephen Foote, Director, Division of Neuroscience and Basic Behavioral Science, National Institute of Mental Health, National Institutes of Health, U.S. Department of Health and Human Services; and Ann Willoughby, Director, Center for Research for Mothers and Children, National Institute of Child Health and Human Development	85
Grossman, Lee, president, Autism Society of America, and an autism parent, Honolulu, HI; Belinda Lerner, member, Autism Coalition, and an autism parent, New York, NY; Stephen Shore, board member, Unlocking Autism, Brookline, MA; and Doug Compton, scientific director, Cure Autism now Foundation, New Jersey	27
Letters, statements, etc., submitted for the record by:	
Burton, Hon. Dan, a Representative in Congress from the State of Indiana:	
Information concerning thimerosal	76
Prepared statement of	6
Boyle, Coleen, Associate Director for Science and Public Health, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, prepared statement of	88
Clay, Hon. Wm. Lacy, a Representative in Congress from the State of Missouri, prepared statement of	146
Compton, Doug, scientific director, Cure Autism now Foundation, New Jersey, prepared statement of	59
Davis, Hon. Thomas M., a Representative in Congress from the State of Virginia, prepared statement of	145
Foote, Stephen, Director, Division of Neuroscience and Basic Behavioral Science, National Institute of Mental Health, National Institutes of Health, U.S. Department of Health and Human Services, prepared statement of	104
Grossman, Lee, president, Autism Society of America, and an autism parent, Honolulu, HI, prepared statement of	31
Horn, Hon. Stephen, a Representative in Congress from the State of California, "For the Love of Zachary"	19
Lerner, Belinda, member, Autism Coalition, and an autism parent, New York, NY, prepared statement of	41
Morella, Hon. Constance A., a Representative in Congress from the State of Maryland, prepared statement of	68
Shore, Stephen, board member, Unlocking Autism, Brookline, MA, prepared statement of	50
Smith, Hon. Christopher H. Smith, a Representative in Congress from the State of New Jersey, prepared statement of	148
Waxman, Hon. Henry A., a Representative in Congress from the State of California, prepared statement of	81

THE AUTISM EPIDEMIC—IS THE NIH AND CDC RESPONSE ADEQUATE?

THURSDAY, APRIL 18, 2002

House of Representatives,
Committee on Government Reform,
Washington, DC.

The committee met, pursuant to notice, at 1 p.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Gilman, Morella, Shays, Horn, Jo Ann Davis of Virginia, Weldon, Waxman, Maloney, Norton, Cummings, Kucinich, and Watson.

Staff present: James C. Wilson, chief counsel; S. Elizabeth Clay, Scott Feeney, and John Rowe, professional staff members; Jennifer Klute, counsel; Robert A. Briggs, chief clerk; Robin Butler, office manager; Elizabeth Crane, legislative assistant; Elizabeth Frigola, deputy communications director; Joshua Gillespie, deputy chief clerk; Susie Schulte, staff assistant; Leneal Scott, computer systems manager; Corinne Zaccagnini, systems administrator; Sarah Despres, minority counsel; Josh Sharfstein, minority professional staff member; Jean Gosa and Earley Green, minority assistant clerks; and Teresa Coufal, minority staff assistant.

Mr. Burton. Good afternoon. A quorum being present, the Committee on Government Reform will come to order.

I ask unanimous consent that all Members' and witnesses' written and opening statements be put in the record. Without objection, so ordered.

I ask unanimous consent that all articles, exhibits, and extraneous and tabular material referred to be included in the record. Without objection, so ordered.

Today we are here to talk about the autism epidemic. I use the word "epidemic" for a good reason. Typically, we think about epidemics in terms of infectious diseases. However, a condition is considered epidemic when it occurs suddenly in numbers that are clearly higher than normal.

Ten years ago only 1 in 10,000 children were thought to be autistic. When we began our investigation in 1999, that number was estimated to be 1 in 500. That is a 20 times increase. However, the number today appears to be even higher.

The Center for Disease Control [CDC], conducted two prevalence studies. The study in Brick Township, NJ, found that 1 in 181 children between the ages of 3 and 10 were diagnosed with autism, and 1 in 128 were diagnosed with autism spectrum disorders. An as yet unpublished study conducted in 1996 in Atlanta, GA, found that 1 in 294 children ages 3 to 10 had autism.

The National Institutes of Health [NIH], places the estimate at 1 in 250 children, and boys are affected four times more often than girls. That means that about 1 in every 156 boys in this country between the ages of 1 and 10 are autistic.

Unfortunately, the unexpectedly high rates in Georgia and New Jersey are not isolated examples. This school year there are 3,789 individuals with autism in Indiana schools. This is up from 116 just 12 years ago, 116 to 3,789.

A recent news article out of Thailand indicates that there are 100,000 children in Thailand with autism. In 1999, the East Surrey Health Authority in the United Kingdom stated that the prevalence of autism in their district was 1 in every 69 boys.

In the 60 years since autism was first described, we have not yet figured out what causes it. We do not know if classical autism and late-onset autism are the same conditions or two different conditions with similar symptoms. We have come a long way in 60 years. Doctors no longer blame the condition on bad mothering. But we have a lot more work to do before we can pat ourselves on the back for our accomplishments.

Is our investment in research on autism on a comparable level with other epidemics? This is very interesting. Are the CDC and NIH funding studies that will help prevent or cure autism? Is their research adequately addressing the medical issues associated with autism such as food allergies, chemical sensitivities, and autistic enterocolitis? Is the information about autism provided by our government adequate and useful to families?

The CDC will testify today that they plan on spending $11.3 million on autism this year and $10.2 million on autism next year. We compared that to two other conditions that have been declared epidemics: diabetes and AIDS. Both of these conditions can be devastating. Both deserve sufficient research dollars to develop treatments and look for cures.

The CDC is spending over $932 million on the AIDS epidemic this fiscal year. Compare that to $11 million for autism. AIDS deserves attention—don't get me wrong—and so does diabetes, which both Secretary Thompson and the former Surgeon General declared an epidemic. CDC this year will spend just over $62 million on diabetes. The autism epidemic, just like the diabetes and AIDS epidemics, is no less deserving. Yet, the CDC's spending for autism is almost 80 times less than that for AIDS. And CDC's spending for autism is five times less than that of diabetes. CDC should be committing more research money for autism, and we are going to work on that.

Now let's look at the National Institutes of Health. We have got some charts up there on the wall which you can look at. The NIH is the premier biomedical research institution in the world. Congress has worked hard to double the NIH's budget. Their total budget this year is $27 billion. We are committed to funding research to help cure crippling diseases.

The NIH will testify today that their commitment to researching autism has grown dramatically in the last few years. In fiscal year 1997, the NIH investment in autism research was only $22 million.

Last year that number had grown to $56 million, in large part because of the Congress.

That's good, but let's put that into perspective. At the same time the NIH is spending $56 million on autism, a condition that affects 1 in every 250 children in this country, they are investing over $2.2 billion in AIDS research. The rates of diabetes increased by 49 percent between 1990 and the year 2000. Diabetes is a devastating condition in the Native American community and of increasing concern in the African American and pediatric populations. This year the NIH investment for diabetes is $688 million, and compare that to the $56 million that they are going to spend on autism, and compare that to the huge money that is being spent on the AIDS research.

I believe these numbers speak for themselves. Funding in basic and clinical research into autism needs to be expanded dramatically. We have an epidemic on our hands, and we in Congress need to make sure that the NIH and CDC treat this condition like an epidemic and put their efforts into doing several things: First, to find out the causes of the epidemic. Second, determine how to stop the epidemic in its tracks. Third, to evaluate treatment options. And, fourth, to look for a cure.

When we first began looking at this issue, we heard from thousands of families. Many told us their children were absolutely normal until they were vaccinated, and that just a few days or weeks after they became vaccinated they became autistic. We also heard about a dramatic similarity in these late-onset autism cases. Many of these children have unusually high levels of heavy metals in their systems. They have immune system irregularities. They have unresolved yeast infections. Eating foods that contain wheat or dairy may result in a rapid deterioration of behavior. Exposure to many chemicals, even perfumes, can have the same adverse effect. Many have chronic diarrhea. NIH and CDC need to fund research to get answers to all these issues.

One of the things that concerns me is that it seems that many of these children, if we tested hair samples, urine samples, blood samples, could give us an idea of whether or not they have mercury in their systems, and to what degree, and whether or not there are other toxic chemicals that may be in their systems that could be found through these tests.

Autism has personally affected my family, and many of you already know that. My grandson Christian was normal and healthy until his second year of life. He walked, he talked, he made eye contact, he enjoyed going to the mall, and all the other things that 2-year-olds do. And then suddenly, shortly after receiving his mandated immunizations, he became a different child. He no longer spoke. He would not look anyone in the eye. He cried endlessly. He banged his head against the wall. He began running around flapping his hands, and he had chronic diarrhea and severe bowel problems. We now know that he was suffering from an adverse reaction to his vaccines. We also know that he may have received more mercury in his vaccines than is considered safe, way more than safe, by Federal standards. This mercury toxicity was contributing to the adverse reaction.

So far, the NIH and the CDC discount any potential connection. The Institute of Medicine has stated that the available research data is insufficient to prove or disprove a connection between autism and either the MMR vaccine or thimerosal, which is the preservative put in most children's vaccines. But they say the link is biologically plausible. The IOM called for more research in this area. One of the reasons we are here today is to make sure that research gets done, and gets done now rather than 10 years from now, when many more thousands of children become autistic.

When you are a parent, whether your son or daughter is autistic from birth, because of genetics, or because of some environmental exposure such as vaccines or maybe something else, you are facing a challenge more difficult than a 500-piece puzzle. You are faced with putting the puzzle of your child's life together one piece at a time.

Do you put special locks on your doors and windows and add an alarm system because you're afraid the child will wander away from your home? Do you need to put a lock on a cabinet in your kitchen to keep the foods that set your children into a spiral out of their reach? What medicines or dietary supplements will your child need? How do you find services? Does your child need to learn sign language? Do you need ABA or other behavioral therapy? Where can you find a qualified speech therapist? How are you going to pay for all of this? How are you going to get through the school services maze? How will you find time for your other children?

What happens when the child grows up? And that's something our government needs to think about. One in 250 children are becoming autistic, and we are not doing a great deal of dealing with that problem right now, but they are going to grow up and then they are going to be adults with autism. Now if you have 1 in 250 people in this society that's autistic down the road, because we haven't done our job now, how are we going to take care of it? How are we going to take care of all the health care needs besides autism at the same time as taking care of the burden they are going to be on society? And our medical and research people need to address that issue. These are all dilemmas that parents face now.

In addition to witnesses from the NIMH and CDC, I am pleased that we have several autism organizations represented here today. We were not able to have all of the organizations testify at the table, but I hope that each will submit written statements for the record.

Mr. Lee Grossman of Hawaii is our first witness. He is the president of the Autism Society of America and has a son with autism.

Ms. Belinda Lerner of New York is a member of the Autism Coalition and has a son with autism. While having a child with autism may be her toughest battle, Ms. Lerner is not a stranger to tough battles; she is the first female attorney to work for the National Football League. Those are big guys. [Laughter.]

Mr. Stephen Shore of Brookline, MA, is a board member of Unlocking Autism. Mr. Shore, who did not speak the first 4 years of his life, has Asperger's disease, a condition on the autism spectrum. Mr. Shore is a success story. Because of his mother's drive and dedication, Mr. Shore is a doctoral candidate at Boston University. That's very commendable. He gives all families with autistic children hope.

Mr. Doug Compton is the science program director of Cure Autism Now and the father of an autistic child.

I look forward to hearing from our witnesses today. Our hearing record will remain open until May 3rd.

[The prepared statement of Hon. Dan Burton follows:]

Opening Statement
Chairman Dan Burton
Committee on Government Reform

April 18, 2002 Hearing

The Autism Epidemic –
Is the NIH and CDC Response Adequate?

2154 Rayburn House Office Building
Washington, D.C.
1:00 pm

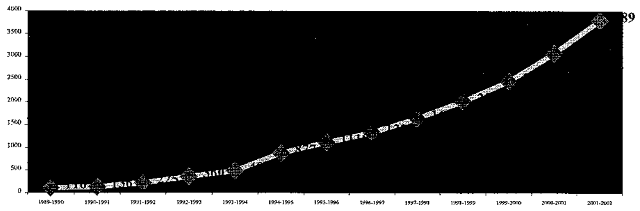
Today, we are here to talk about the autism epidemic. I use the word epidemic for a good reason. Typically we think about epidemics in terms of infectious diseases. However, a condition is considered epidemic when it occurs suddenly in numbers that are clearly higher than normal.

Ten years ago only 1 in 10,000 children were thought to be autistic. When we began our investigation in 1999 that number was estimated to be 1 in 500. However, the number today appears to be even higher. The Centers for Disease Control and Prevention (CDC) conducted two prevalence studies. The study in Brick Township, New Jersey, found that 1 in 181 children between three and ten were diagnosed with autism. And 1 in 128 were diagnosed with autism spectrum disorders.

An as yet unpublished study conducted in 1996, in Atlanta, Georgia, found that 1 in 294 children ages three to ten had autism. The National Institutes of Health (NIH) places the estimate at 1 in 250 children. And boys are affected 4 times more often than girls. That means that about 1 in every 156 boys in this country is autistic.

Unfortunately, the unexpectedly high rates in Georgia and New Jersey are not isolated examples. This school year, there are 3,789 individuals with autism in Indiana schools. That is up from 116 just 12 years ago.

Individuals with Autism in the Indiana Educational System



A recent news article out of Thailand indicates that there are 100,000 children in Thailand with autism. In 1999, the East Surrey Health Authority in the United Kingdom stated that the prevalence of autism in their district was 1 in every 69 boys.

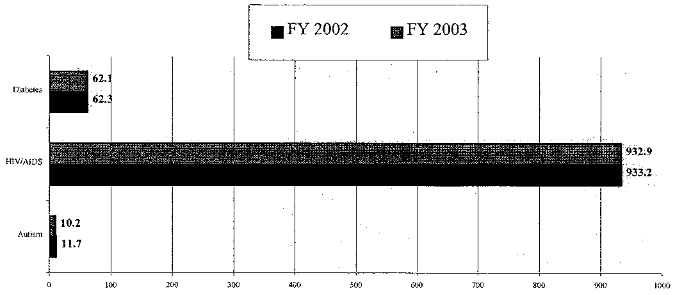
In the sixty years since autism was first described, we have not yet figured out what causes it. We do not know if classical autism and late-onset autism are the same conditions or two different conditions with similar symptoms. We have come a long way in sixty years. Doctors no longer blame the condition on bad mothering. But we have a lot more work to do before we can pat ourselves on the back for our accomplishments.

Is our investment in research on autism on a comparable level with other epidemics? Are the CDC and NIH funding studies that will help prevent or cure autism? Is their research adequately addressing the medical issues associated with autism such as food allergies, chemical sensitivities, and autistic entercolitis? Is the information about autism provided by our Government adequate and useful to families?

The CDC will testify today that they plan on spending 11.3 million dollars on autism this year and 10.2 million dollars next year. We compared that to two other conditions that have been declared epidemics - diabetes and AIDS. Both of these conditions can be devastating. Both deserve sufficient research dollars to develop treatments and look for cures.

The CDC is spending over 932 million dollars on the AIDS epidemic this fiscal year. AIDS deserves attention - don't get me wrong. And so does diabetes, which both Secretary Thompson and the former Surgeon General declared an epidemic. CDC this year will spend just over 62 million dollars on diabetes. The autism epidemic just like the diabetes and AIDS epidemics, is no less deserving. Yet, CDC's spending for autism is almost 80 times less than that for AIDS. And CDC's spending for autism is 5 times less than that of diabetes. CDC should be committing more research money to autism.

CDC Funding for 3 Epidemics (Estimated)
($ in Millions)

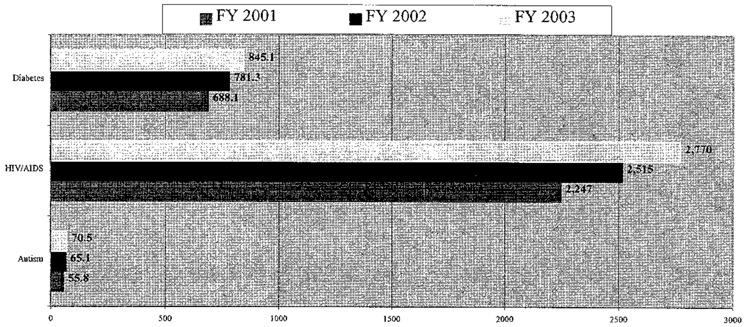


Now let's look at the National Institutes of Health (NIH). The NIH is the premier biomedical research institution in the world. Congress has worked hard to double the NIH's budget. Their total budget this year is 27 billion dollars. We are committed to funding research to help cure crippling diseases.

The NIH will testify today that their commitment to researching autism has grown dramatically in the last few years. In fiscal year 1997, the NIH investment in autism research was only 22 million dollars. Last year that number had grown to 56 million – in large part because of Congress.

That's good, but let's put that into perspective. At the same time the NIH is spending 56 million dollars on autism – a condition that affects 1 in 250 children in this country – they are investing over 2.2 billion dollars in AIDs research. The rates of diabetes increased by 49 percent between 1990 and 2000. Diabetes is a devastating condition in the Native American community and of increasing concern in the African American and pediatric populations. This year, the NIH investment for diabetes is 688 million.

NIH Funding for 3 Epidemics ($ in Millions)



I believe the numbers speak for themselves. Funding into basic and clinical research into autism needs to grow. We have an epidemic on our hands and we in Congress need to make sure that the NIH and the CDC treat this condition like an epidemic and put their efforts into doing several things:

- Find out the cause(s) of the epidemic
- Determine how to stop the epidemic in its tracks
- Evaluate treatment options
- Look for a cure

When we first began looking at this issue, we heard from thousands of families. Many told us their children were absolutely normal until after they were vaccinated. And that days or weeks afterwards they became autistic. We have also heard about a dramatic similarity in these late onset autism cases. Many of these children have unusually high levels of heavy metals in their systems. They have immune system irregularities. They have unresolved yeast infections. Eating foods that contain wheat or dairy may result in a rapid deterioration of behavior. Exposure to many chemicals – even perfumes – can have the same adverse effect. Many have chronic diarrhea. NIH and CDC need to fund research to get answers to all of these issues.

Autism has personally affected my family. My grandson Christian was normal and healthy until his second year of life. He walked, he talked, he made eye contact, he enjoyed going to the mall. And then suddenly, shortly after receiving his mandated immunizations, he became a different child. He no longer spoke. He would not look anyone in the eye. He cried endlessly, banging his head. He began running around flapping his hands. We now know he was suffering from an adverse reaction to his vaccines. We also know that he may have received more mercury in his vaccines than is considered safe by Federal standards. This mercury toxicity was contributing to the adverse reaction.

So far, the NIH and the CDC discount any potential connection. The Institute of Medicine (IOM) has stated that the available research data is insufficient to prove or disprove a connection between autism and either the MMR vaccine or thimerosal-containing vaccines. But they say the link is biologically plausible. The IOM called for more research in this area. One of the reasons we're here today is to make sure that research gets done and gets done now rather than ten years from now.

When you are a parent, whether your son or daughter is autistic from birth, because of genetics, or because of some environmental exposure such as vaccines or maybe something else, you are facing a challenge more difficult than a 500-piece puzzle. You are faced with putting the puzzle of your child's life together one piece at a time. Do you put special locks on your doors and windows and add an alarm system because you're afraid you child will wander away from your home? Do you need to put a lock on a cabinet in your kitchen to keep the foods that set your child into a spiral out of their reach? What medicines or dietary supplements will your child need? How do you find services? Does your child need to learn sign language? Do you need ABA or other behavioral therapy? Where can you find a qualified speech therapist? How are you going to pay for all of this? How are you going to get through the school services maze? How will you find time for your other children? What happens when he grows up? These are all dilemmas that parents face.

In addition to witnesses from the NIH and CDC, I am pleased that we have several autism organizations represented today. We were not able to have all the organizations at the table. But I hope that each will submit written statements for the record.

Mr. Lee Grossman of Hawaii is our first witness. Lee is the President of the Autism Society of America and has a son with autism.

Ms. Belinda Lerner of New York is a member of the Autism Coalition and has a son with autism. While having a child with autism maybe her toughest battle, Ms. Lerner is not a stranger to tough battles - she is the first female attorney to work for the National Football League.

Mr. Stephen Shore of Brookline, Massachusetts, is a Board member of Unlocking Autism. Mr. Shore, who did not speak the first four years of his life, has Asperger's Disease - a condition on the autism spectrum. Mr. Shore is a success story. Because of his mother's drive and dedication, Mr. Shore is a doctoral candidate at Boston University. He gives all families with autistic children hope.

Mr. Doug Compton is the science program director of Cure Autism Now and the father of an autistic child.

I look forward to hearing from our witnesses today. Our hearing record will remain open until May 3.

I now recognize the ranking minority member, Mr. Waxman for his opening statement.

Yesterday I received from the Riley Children's Hospital in Indianapolis the following update that I would like to include in the hearing record.

Treatment of Autism
at Riley Hospital for Children

The Christian Sarkine Autism Treatment Center

Riley is Indiana's only acute care children's hospital, is centrally located in Indianapolis, is affiliated with the Indiana University School of Medicine, and is home to the only comprehensive collection of pediatric specialists in the state. One of its many programs of excellence is the Christian Sarkine Autism Treatment Center. To be considered a center of excellence, a program must represent the following:

1. Clinical superiority as defined by the presence of staff of national stature rendering treatment in accordance with the most up to date standards known to the field. In addition, these individuals must be supported by a full range of diagnostic and therapeutic modalities, available in-house on an uninterupted basis.

2. Training programs designed to be a source for populating respected programs nationally with highly qualified specialists capable of carrying on the work of the center in other locations. All residencies must be fully accredited by the Americal College of Graduate Medical Education (ACGME).

3. Research programs that regularly contribute to the body of knowledge through the conduct of peer reviewed trials and publications.

4. Community service provided through public education and advocacy on behalf of the children and families served by the center.

The Christian Sarkine Autism Treatment Center meets all of these criteria. It is among the five largest centers in the nation, and is led by Dr. Christopher McDougle one of the nations most respected experts in autism spectrum disorders. Riley's residency in pediatrics is one of the largest in the nation, and it along with pediatric neurology, and child psychiatry are all fully accredited by ACGME. Fully seventy percent of the pediatricians in the state have received some or all of their training at Riley. Riley's research programs (many under the auspices of the Indiana University School of Medicine) are among the top 20 nationally in funding for pediatrics by the National Institutes of Health. Drs. McDougle, Posey, and Swiezy and other members of the staff regularly publish in the nations most respected scientific journals, and are participants in numerous individual and multi-center clinical trials. Lastly, the staff of the Christian Sarkine Autism Treatment Center maintain a speaker's bureau, and frequently testify before various legislative bodies on behalf of the needs of children with autism, hold forums for schools, and give lectures for an array of public and private agencies providing community services.

Autism

Autism is a disorder that appears at about the second year of life, and for which there is no known cure. It was first described in the literature in the 1940's, and is now recognized not as one condition, but rather as a spectrum of disorders that have subtle differences. Autism creates profound disturbances in the child's behavior, causing lifelong effects that will impede their ability to function properly at all levels. Most current research is focused on population studies attempting to determine the causes and origin of autism, and on medications and other therapies designed to minimize its effects.

The Need for Further Investment

The program at Riley Hospital for Children is by far the largest provider of services to the families of children with autism. Most providers in the state have a small number of children with autism in their practices, but rarely do they accept more than a few since these cases are difficult, time consuming, and poorly reimbursed. Almost all children with autism consume the lifetime benefit of their insurance plans, and ultimately most come to depend on Medicaid for coverage. Typically then, families come to Riley either directly or by referral seeking expert services that cannot be found in their local communities. As a result, Riley like most nationally recognized centers, has a significant backlog in its caseload. New patients often must wait ten months for their first appointment.

Clinical Progress

Yet there are some prospects for improvement in this picture. In late 2002 or early 2003, the Christian Sarkine Autism Treatment Center will move to a new and greatly expanded location within the Riley Outpatient Center. At a total cost of $2.3 million, the center and its affiliated Child Psychiatry Clinic will be housed in a state-of-the-art facility capable of accommodating an expanded treatment staff. Close to $1 million of this project has been funded through a federal appropriation.

In anticipation of this new facility, the Department of Child Psychiatry has embarked on a recruitment campaign which to date has resulted in the following actual and planned improvements in staffing:

1. One behavior therapist joined the staff in January 2002 whose focus will primarily be devoted to providing services in homes and schools. A second therapist will join the staff in July 2002.
2. A doctoral level pediatric psychologist will join the staff in July 2002, bringing added depth in behavioral therapy.
3. Two physicians have been able to increase their time commitment to the program. This permits the opening of additional appointment times for patients on the waiting list.
4. A master's prepared social worker joined the staff in July 2001 whose activities are focused on development of parent and sibling support groups.
5. In July and August of 2001, two scientists were employed to broaden the depth of the research program.
6. In July 2002 a speech therapist will be added to the center's staff, and plans are underway to add an occupational therapist. These positions will render therapies designed to address the physical effects of autism.
7. An additional medical resident has joined the program. It is expected that this individual will join the faculty in July 2003 upon completion of their fellowship.

The addition of these positions would not have been possible without the receipt of two federal appropriations.

Progress in Research

Substantial efforts to expand the research program at Riley are also underway. An application has been prepared for a National Institutes of Mental Health autism center grant ($1 million/year for five years), and for renewal of the NIMH's Rupp Autism Grant.

New studies have been initiated in the Christian Sarkine Autism Treatment Center including research into neuroimmunologic activity in children with autism. In particular, the center has been studying measures of kynurenine and interferon, which are potential markers of inflammatory disease including viral-related etiologies. Staff are also comparing the rates of autoimmune disorders in primary relatives of children with autism, children with known autoimmune disorders, and a control group. It is anticipated that this endeavor will produce immune-related therapies for appropriate subjects, and is the subject of an application for a National Institutes of Health Autism Center of Excellence grant.

The staff have also participated in a number of individual and multi-center clinical trials of the effects of medication. The largest study of Risperidone ever completed was performed by Riley staff in collaboration with other sites among the NIMH-sponsored Research Units on Pediatric Psychopharmacology. Additional work has been done with novel agents, specifically Mirtazapine and D-Cycloserine

Articles published by center staff have recently appeared in the following nationally recognized literature:

Journal of Psychpharmacology
Journal of Autism and Developmental Disorders
Journal of Child and Adolescent Psychopharmacology
Pharmacology Biochemistry and Behavior
Harvard Review of Psychiatry
Journal of Interferon and Cytokine Research
Child and Adolescent Disorders

Continuing the Mission

The progress made in the past year could not have been accomplished without financial assistance from several federal appropriations. To continue this important work, Riley Hospital for Children and the Christian Sarkine Autism Treatment Center request additional funding in the amount of $500,000 to be used to support personnel expenses in the clinical and research settings. The funding will permit continued employment of the individuals engaged in the past year, as well as new additions including one physician, an occupational therapist, and other professional staff.

Mr. BURTON. Mr. Waxman is not yet here.

Mr. Gilman, do you have a statement you would like to make?

Mr. GILMAN. I do. Thank you, Mr. Chairman. I want to thank Chairman Burton for conducting this important hearing regarding NIH and CDC's response to the rising rate of autism in our Nation.

I recently met in my constituency with Jeanine Conklin, a mother to Daniel, her 5-year-old autistic son. Listening to her explain the obstacles that her family must face each and every day reaffirmed by commitment to this issue. It is essential that there be continued research of and funding for learning more about how this affliction manifests itself and how it can be prevented, and how to properly educate the public. It is important to understand how we define autism, why the autism rate is increasing, and how we can support effective research that will benefit those who are already afflicted by autism.

Autism makes it difficult for an individual to interact with people and their environment. In some cases those with the illness may behave in an aggressive or self-injurious manner. It occurs in people of all races, ethnicities, and socioeconomic backgrounds. A better understanding of the origins of the disease is crucial to introducing new and effective treatments.

As Chairman Burton noted, autism has afflicted 1 in 500 children in the United States. However, the CDC shows that even higher rates occur in some specific locales such as Atlanta, GA, Brick Township, NJ, where the autism rates are 1 in 94 and 1 in 128, respectively.

These alarmingly high rates have lead to several inquiries into the contributing factor of the disease, including, but not limited to, childhood vaccines and some of the environmental factors. Many of the symptoms of autism are the same as mercury toxicity. Through an FDA review, it was learned that the amount of mercury in mandated vaccines that children were receiving in the first 6 months of their lives exceeded guidelines that were established by the Environmental Protection Agency and validated through an Institute of Medicine review.

We have convened here today to monitor whether NIH and the CDC have satisfactorily responded to the challenge of autism research. More specifically, we would like to know if they made headway into IOM's research recommendations, research to determine how children metabolize and excrete metals, particularly mercury; continued research on theoretical modeling of ethyl-mercury exposures and careful, rigorous, and scientific evaluations of chelation, when used in children with neurodevelopmental disorders, especially autism.

Our committee's oversight is an essential component to increasing communication. Autism is a disease that paralyzes communication. We cannot afford to paralyze the communication between our medical community, our government sector, and those families who have been affected by autism. We owe it to the American families like the Conklins in my area to do everything in our power to ensure that the Federal Government continues its commitment to autism, to research and discovery.

As a member of our Congressional Caucus on Autism, I am extremely interested in the testimony that our witnesses will have to present to us today. I want to thank Chairman Burton again for his dedication to the health and safety of our Nation's children.

Mr. BURTON. Thank you, Mr. Gilman.

Let's see, Dr. Weldon.

Dr. WELDON. Hi, Mr. Chairman. I do not have an opening statement, but I just want to again thank you for bringing the spotlight of congressional scrutiny onto this very critical issue of autism in America. I believe it to be a forgotten and neglected disease for too long. Thank you for your leadership on this.

Mr. BURTON. Thank you, Dr. Weldon. Mr. Shays.

Mr. SHAYS. Thank you, Mr. Chairman. Mr. Chairman, no prepared statement other than to thank you for having this hearing and to say that, like a number of Members of Congress, I have a very sizable number of autistic young and old in my district. It is far more noticeable than in the past, and I am deeply concerned about it. I can't imagine what it must be like for a parent to hold a child and just be hungry for some type of response of recognition. So I just thank you.

I know we are all wrestling with this. I know nobody has the answers, but together I hope we are able to find some.

Mr. BURTON. Thank you, Mr. Shays. Ms. Davis. Mr. Horn.

Mr. HORN. Thank you, Mr. Chairman, for this continuing effort to get at autism. I would like to have in the record a piece called "Medicine for the Love of Zachary," which was Zach and Karen London, and she affected 400,000 people nationwide with her crusade. I think you would find it very inspiring.

Mr. BURTON. Thank you, Mr. Horn. We will put that in the record, without objection.

[The information referred to follows:]

For the Love of Zachary

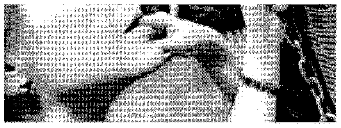
How a mother's fierce will helped bring hope to autistic children everywhere By Beth Kephart*

Zack and Karen London: Autism *is an affliction that affects* ***400,000 people*** *nationwide, each one unique.*

It was the parking lot that won Zach's heart—the glinting alphabet of cars. He was past his first birthday, not speaking yet, still somewhat unsteady on his toes, but the dark-haired, big-eyed boy still had the power to make his passions known, and his joy, just then, sprang from cars. Not their colors, shapes or personalities, not their relative alignments between the striped dividing lines, but the embossed hieroglyphics of the vehicles' license plates, which Zach would crouch down to trace with the appreciative tip of his index finger. It gave him pleasure. It left his finger blackened with soot. It was, for him, a carnival of delights, while nearby his mother stood and watched, coaxed Zach forward, tried not to add this newest oddity to the sum of other disparate, troubling parts: Zach's habit of assembling complex puzzles upside down. His surprising facility for rapidly reverse-ordering the magnetic letters that clung to the refrigerator door. His ability to swing for hours on end—satisfied, not talking, eerily calm. Zach wasn't like other children his mother had known, but then again, every child is unique. And though typical play and speech did not emanate from Zach, something ineluctable did: a tenderness, a deep-reaching affection from which his mother and father took solace.

Still, Zach's parents, Karen Margulis London, a University of Pennsylvania-trained corporate attorney, and her husband, Eric, a respected psychiatrist, found themselves incapable of keeping their worries at bay. The "A word," they called it, unable even to enunciate autism to one another. A pediatrician urged Karen and Eric to continue observing, and faithfully, horrified, they did. All throughout his second year of life, Zach slipped farther away—tuning in and out, paradoxically, to sounds, entrancing himself with the dance of his fingers, falling in love with TV. Two months shy of his second birthday, just days before Karen gave birth to the Londons' second child, Rachel, the family's worst fears were confirmed by a team of specialists at Children's Hospital: Zach did indeed have autism. The word, like a manacle, tightened its grip and stayed.

A mythology of sorts has grown up around autism, a range of theories, suggestions, false science. Popular culture gives us autism at its extremes. We're introduced to Raymond of Rain Man, who with his superlunary mind could perform seemingly impossible feats of mathematics and recall. We know of the children in made-for-TV movies who can decode the clues of otherwise elusive, perfect crimes or



who, on the other end of the spectrum, are consigned to a life of miserable, head-banging moaning. We know the stories Oliver Sacks tells so well, with his artful, compassionate, ultimately honest prose.

But what we don't know yet, not really, is what autism is, where (precisely) it comes from, how to cure it, whether indeed it should be cured. It was Dr. Leo Kanner of Johns Hopkins University who, in the 1940s, first began to systematically separate this particular breed of "disturbance" from other psychoses. Hans Asperger, a Viennese pediatrician working independently at the same time, found himself fascinated as well with this special class of patients and their profoundly original qualities.

Even from its classified start, autism defied easy generalizations and thwarted desires for a magic, curing bullet. Along the way, theories about education and intervention have multiplied, promises about "fixes" have been made and broken, entire advocacy camps have been formed—leaving parents of newly diagnosed children with a swelter of possibilities and half-hopes to slog through. Simply getting to the next day can in itself be an act of heroics.

Today, many physicians talk, if still somewhat inconsistently, about the continuum of autism—about a spectrum of disorders. They speculate about causes—investigating genes, environmental toxins, viruses, even childhood vaccines. They talk about the frustrations implicit in a disorder that is neurologic but must nevertheless be diagnosed by observing a young child's behavior. Estimates vary widely, but most experts believe that autism disorders, three to four times more prevalent in boys than in girls, afflict 400,000 individuals nationwide, occurring in one of nearly every 500 births. This makes autism far more prevalent than, for example, cystic fibrosis or multiple sclerosis. Finally, they refer to the Diagnostic and Statistical Manual, IV, which suggests the following, not necessarily enlightening, criteria for diagnosing autism: severely impaired social interaction, severely impaired communication and imagination, extremely limited interests and activities first observed in infancy or early childhood. If anything is true about the "A word," it is this: Every child diagnosed presents an utterly original matrix of deficits and strengths, demanding a certain artistry on the part of parents and caregivers, a willingness to cast one's whole heart upon the sea of improbable possibilities.

In the end, it doesn't matter what label has been meted out. What matters is that the entire trajectory of a family has been changed irrevocably. What matters is what that family does with the news it has been given, how quickly it can bury its aches and confusion and reach out to help the child. Many parents do indeed rise to extraordinary heights. Some, like the Londons, go further, broadening their quest for healing so as to open more doors of hope for the next generation of children.

Petite and dark-haired, emanating a Wall Streeter's smarts and a poet's passion, Karen London, now 43, was just a galley proof away from publishing a key article concerning new securities regulations when Zach's diagnosis threw her life for a curve. Hollowed out and broken-hearted, she returned to her office and called her boss. Within a half hour, she was gone, leaving her desk, her filing cabinets, the pictures on her office walls untouched. She left corporate life with her briefcase in hand and never once looked back. The briefcase, still full of personal papers, remains locked and dusty to this day.

For the first few years, Karen directed her energies toward her children—finding the best therapists and school for Zach and paying close attention to her newborn daughter. At eight o'clock each day, a bus took Zach to his school, leaving Karen at home to play with Rachel. At three, Zach's bus would bring him back home, Rachel would be placed in the care of a sitter, and Karen and Zach would begin their collaborative work. Visual word recognition: Point to the cup, Karen would say. Point to the apple. Point to the hat. What is it? Hat. What is it? Cup. The therapy reflected a mélange of ideas—strategies culled from the Princeton Child Development Institute, where Zach was attending school, and suggestions put forth by Karen's husband, Eric, then specializing in substance abuse. It was Eric who realized that Zach was capable, at age three, of decoding written words even though he could not speak. It was Eric who suggested, among other things, that the Londons employ sign language to give Zach yet another layer of information.

"We were experimenting," Karen says, her chin resting in the cup of her hands, her voice quiet, her story told with such extraordinary care that when it is played back over the tape recorder later that night, one finds not a single "um," no idle chitchat, no ounce of self-pity or self-aggrandizement. "We were pulling out all of the stops. The most basic accomplishment—producing a two-syllable word, learning how to use a spoon or catch a ball—would fill me with the same conflicted feeling: sadness that we had to so painstakingly teach our child the things that come naturally to others, and relief, the sense of a miracle, that Zach had in fact acquired another skill."

Not until Rachel was a year old, sociable and talking in complete sentences, did Karen let herself believe that her daughter had emerged unscathed. It wasn't until then that this lawyer-abruptly-turned-full-time-mom grew increasingly alert to, and bothered by, the absence of organized autism science. The rules of her entire life had changed, and her intellect—still keen, still hungry—had become engaged with a riddle, a challenge, a problem that had not yet been solved.

Karen's sense that autism was being ignored by the scientific community was reinforced by Eric, whose personal and professional eagerness to immerse himself in the field was disappointed at almost every turn. Major psychiatry meetings, for example, yielded nothing about biomedical research. Real answers to difficult medical questions were hard to come by. And as Eric's own patient population began to include an increasing number of individuals with autism, he grew intensely frustrated by the paucity of pharmaceutical options.

"Resourceful psychiatrists have been borrowing drugs from other disorders for a couple of years now," says Eric, 46. "But they haven't, to date, been given a pharmacological intervention that was designed and developed for those with autism." And since some individuals with autism share many symptoms with persons with learning disabilities, attention deficit disorder, schizophrenia and mental retardation, the emergence of such a new breed of pharmacological therapy could, says Eric, provide a new way of life for literally millions.

But how does one stir the minds, the imaginations, the hearts of those in a position to fund and research such a therapy? Less than half a million individuals in the United States are autistic, and without clearly defined protein "target" molecules around which medicinal chemists might design their research programs, big pharma has stayed notoriously shy of a field of study some describe as the Rosetta stone of human neurobiology. Parents, by and large, have not conceived of a role for themselves on a mountain that industry has deemed too steep to climb.

In November 1993, Arvin Mirow, a childhood friend of Eric's and a geneticist and researcher, made a stop at Karen and Eric's Princeton household. Under his arm he toted three tomes acquired from his most recent neuroscience conference, which he stacked precariously on the kitchen table. Spontaneously, suspiciously, the three longtime friends began to pour through the 14,000 abstracts within those volumes—looking the word "autism" up in the indexes and finding but 11 mentions overall. Dismay and discouragement and more than a modicum of disgust filled the room. "Why isn't anyone researching autism?" Karen remembers asking out loud. And that's when her friend said what Karen calls "his famous words": "Do something about it, if you are so concerned."

Late at night, with the children asleep, Karen began investigating the hows and whats of some of the nation's leading disease-specific nonprofit organizations, stopping frequently to consider the implications for a still-imaginary organization devoted to advancing autism research by providing seed money for pilot studies that researchers could then take to organizations like the National Institutes of Health (NIH). During the day, while her children were at school, she got involved in local autism organizations, getting on the board, going to conferences, quietly asking her own difficult questions. In between, she listened, feeling helpless, to the stories Eric was telling about his growing caseload of autism patients, to the heartache her friends were conveying, to Zach himself as he fought for each and every one of his spare, floating, disoriented words.

Soon enough, Karen and Eric were dining with Dr. Margaret Bauman, a pioneering Harvard researcher, inquiring about whether an organization such as the one the Londons had started to construct in their minds was both necessary and plausible. Still, Karen harbored doubts as to whether she could make that kind of commitment.

The next day, however, Dr. Bauman, at the close of a keynote presentation the Londons were attending, reported to the audience that a young couple was starting a national organization, pointing Eric out to the crowd. Within moments, Eric was surrounded by volunteers, a group of grandmothers from Long Island.

"We had gone," Eric recalls now, a glimmer of bemusement in his tired eyes as he sits at is kitchen table nursing a cold cup of coffee, "well past the point of no return."

In July 1994, the Princeton-based National Alliance for Autism Research was officially incorporated. With Zach in school and Rachel about to enter full-time kindergarten, Karen remade her basement into a provisional office.

With 22 leaders from the nation's top universities and research centers signed on for "a review board without peer," Karen assembled a board of trustees, calling on doctors, journalists, professors and Philadelphia Eagles owner Jeffrey Lurie to assume legal and managerial responsibility for the nonprofit's undertakings. At the same time, an honorary board—including Joe Mantegna, Dan Marino, Wynton Marsalis and Temple Grandin — was called on to lend its energies, talents and resources to a variety of fund-raising events in Hollywood and elsewhere. By and large, those asked to serve know autism well —have seen its impact on their siblings, children or friends.

> What we don't **know** yet not really, is what **autism** is, where (precisely) it comes from, how to **cure it**, whether indeed it **should** be cured.

The quest for healing had hardened into an obsession. Building the caliber of organization that would attract monied donors and talented scientists had become, in so many ways, the heart and whole of the Londons. Their dining room became the office annex. Work got done during the day with the children at school, in the evening with the children in bed, on the weekends when Eric, especially, would travel to conferences, evangelical with his news, his hope, his insistence that his colleagues pay heed to the under-researched matter of autism. The psychiatrist and the lawyer had found their true calling.

In January 1995,NAAR, still operating out of the Karen and Eric's basement, prepared and mailed its first appeal letter. By July 1996, with $150,000 in its pockets and a year of careful planning on its side, NAAR announced the availability of funding for biomedical research in autism and sent its first request for proposals to universities and medical institutions across the United States. Six months later, five researchers were awarded $30,000 each. Biomedical research for autism was finally on the map.

Rebecca Landa, Ph.D., who directs autism research programs at Johns Hopkins University, was one of those who gained financial backing—to pursue the first study of siblings of autistic children. "This is the beginning of my life's work," says Dr. Landa. "If we can find early markers in babies at risk for autism, we can help pediatricians refer children for early intervention, even before the parents raise concerns. We can also better tailor the early intervention to the child's needs, so that we are treating the whole child."

Like Dr. Landa, Duke University's Margaret A. Pericak-Vance, Ph.D., a pioneer in gene-mapping projects for Alzheimer's and multiple sclerosis, has been able, through NAAR research monies, to begin exploring the possibility of a specific genetic susceptibility for autism. She has also been able to fulfill one of NAAR's primary goals, by applying for and receiving millions of dollars of government support for projects begun with NAAR monies.

It is now summer 1998, and Karen London is no longer working out of her home, no longer working alone. Thanks to a $500,000 pledge from a private family foundation, NAAR is currently headquartered in a tiny office in Princeton above a small commercial printer. It boasts three computers, a finicky Xerox machine, a few purplish, shockingly well-drawn cartoons by a 10-year-old boy with autism, piles of research papers that threaten to topple from long—but not long enough—tables. David Maxson, formerly executive vice president of the Franklin Institute, has joined the team, and the phones ring at a rather steady pace—calls containing updates of new science, excitement over the $240,000 research fellowship grant just received from Bristol-Myers Squibb, questions about an upcoming fund-raiser. There are queries, too, about the autism tissue program, designed to encourage people who have autism or are related to those who do to help further biomedical research by formally indicating their desire to donate their brain tissue to science postmortem. Attentive to every detail, Karen London is also slightly overwhelmed. So much remains to be done.

"We set out to stimulate research in autism, and we've achieved that goal," she says, checking her watch now, aware of the time, pressed to get too many things done before her children's schools let out at three. "We wanted to bring scientists into this field who have never before researched autism, and of the 10 investigators we funded most recently with $60,000 grants, seven are new to this field. We wanted to encourage research of such high quality that the NIH would pick it up on a larger scale, and of the five 1997 NAAR grant winners, two have received million-dollar funding. We wanted to get the pharmaceutical companies on board, and Bristol-Myers Squibb's recent pledge is an enormous milestone for us."

Still, says Karen, autism biomedical research remains in the early stages. She'd like to see the identification of the genes implicated in autism, the stimulation of medications oriented toward the symptoms of autism, more research on the mix of extant pharmaceutical therapies and their potential applications for those with autism today.

None of this is pie in the sky. Give the researchers five to 10 years, she says, and they will likely give us some answers. One gets the sense this isn't just big hopes talking, not just a parent prayerful. With her even voice, her extreme intelligence, her command of all things pertinent to what was once the "A word," Karen and her ever-growing cadre of colleagues will take this as far as it can go.

Ten-year-old Zachary London remains entranced, today, by his own long fingers, by the melodies of children's songs, by a little stuffed Pooh bear all dressed for Christmas. His special skill with puzzles has long since passed, and he reads at early first-grade level and converses in occasional, basic, rudimentary sentences devoid of any notion of the abstract. His voice is soft as a puff of dandelions; his eyes slide toward a visitor's, then slide away. His very best friend in the world is his eight-year-old sister, Rachel, who, in addition to being an accomplished student and an emerging violinist, takes care to tuck her big brother in each night, to devise games that he can play with her. Zach is not, as Karen says, a child who is likely to be "cured." But while Zach and Rachel are the Londons's inspiration, NAAR is not ultimately about them.

"A whole generation of parents before us fought to get their children with autism in school, and sometimes their kids ended up being 15 and unable to cash in on the battles their parents won," Karen says, finally allowing the heartbreak of her life's endeavor into her voice, her eyes, suddenly standing, biting her lip, looking for what has not eluded her all morning long: the perfect words. "What Eric and I are doing—with a lot of talented people's help—may not help Zach. But there is a lot of sorrow that goes with having a child who is diagnosed with autism, and Eric and I feel very strongly that if you have the capability to move the agenda forward, even just a little bit, then you have the responsibility. ... I'm building something that I hope will be unnecessary as soon as possible. But realistically, I'm planning for an extended future, for a cause and for a mission I pray others will continue."

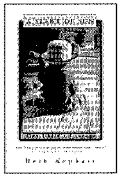
For more information, contact the National Alliance for Autism Research at 1-888-777-*NAAR*, or visit *NAAR*'s web site at www.naar.org.

This article has been reprinted with permission from the September '98 edition of Philadelphia Magazine. Copyright Beth Kephart. Photos by James Wasserman.

If you are considering making a gift to *NAAR* during this holiday season, click here.

▲▲

**Beth Kephart is the author of *A Slant of Sun: One Child's Courage,* a 1998 National



Book Award Finalist!

National Alliance for Autism Research

--updated 01-Apr-99.

A Time for Giving

Karen Margulis London,
President
National Alliance for Autism
Research
414 Wall St. Research Park
Princeton, NJ 08540
1-888-777-*NAAR*
naar@naar.org

Eric Cushing, Director
Nancy Lurie Marks Family
Foundation
1244 Boylston St., Ste. 307
Chestnut Hill, MA 02467
(617) 264-7300
hetal@nlmfoundation.org

NLM FAMILY FOUNDATION HELPS KICK OFF $7.5 MILLION MATCHING GIFT CAMPAIGN FOR AUTISM RESEARCH

$1 Million Challenge Grant Supports National Alliance For Autism Research

Princeton, NJ (Feb. 23, 2000) — The Nancy Lurie Marks Family Foundation of Chestnut Hill, MA, is helping the National Alliance for Autism Research launch a $7.5 million matching gift campaign with a Challenge Grant of $1 million.

Autism is a devastating neurodevelopmental disorder estimated to affect as many as one in every 500 children worldwide. The National Alliance for Autism Research (*NAAR*) is dedicated to finding the causes – and a cure – for the condition by funding and accelerating autism biomedical research.

"The NLM Family Foundation has been a long-time leader in supporting autism research and – to date -- has been *NAAR*'s most generous donor," said Karen Margulis London, *NAAR*'s president and founder. "We are thrilled by its commitment to *NAAR* and its mission."

The Nancy Lurie Marks Family Foundation concentrates its support on autism and related developmental disorders as well as civic, educational and arts projects in the Boston metropolitan area. The Foundation is one of the largest supporters of research and education for autism. In addition to the $1 million Challenge Grant and past support for the *NAAR*, the Foundation also supports the clinical and research efforts of Dr. Margaret Bauman and other noted autism investigators.

"We believe this grant underscores the Foundation's and *NAAR*'s belief in the urgency of significantly increasing the investment in autism research," Ms. London said. "Mrs. Nancy Lurie Marks has truly been an inspiration and leader in her passionate support of research aimed at understanding and finding effective treatments for the spectrum of autism disorders."

NAAR's $7.5 million Major Gifts Campaign—the first such campaign ever on behalf of autism research—has already benefited from the NLM Challenge Grant. *NAAR* has raised an additional $1 million, including a generous donation of $50,000 from the Doug Flutie, Jr. Foundation for Autism.

"In providing this Challenge Grant, our Foundation recognizes *NAAR*'s fine contributions to research in autism," said Eric Cushing, Director of the NLM Family Foundation. "We hope our Challenge Grant will assist in launching *NAAR*'s exciting new Major Gifts Campaign and encourage other substantial donations so that autism truly gets the intensified research attention it merits."

Over the past three years, *NAAR* has committed $1.7 million in grants to 32 scientists in the United States, Italy, Canada and Russia. It makes research awards, up to $100,000 for two years, for innovative proposals highly ranked by its Scientific Advisory Board for scientific merit and promise.

In addition, *NAAR* sponsors conferences for scientists and families, publishes a research newsletter and, in collaboration with the Autism Society of America Foundation, sponsors the Autism Tissue Program, a national outreach program dedicated to encouraging post-mortem brain tissue donation which is critically needed in autism research.

"We must be in the position of availing ourselves of the latest findings in neuroscience research," said *NAAR* Chairman Clarence Schutt, Ph.D, Professor of Chemistry at Princeton University. "The NLM Family Foundation gift and the Major Gifts Campaign are aimed at assuring that no promising autism research goes unfunded."

Headquartered in Princeton, NJ, *NAAR* was founded in 1994 by Karen London and her husband, Dr. Eric London. After their son, Zachary, was diagnosed with autism in 1989, the couple founded *NAAR*, the first nonprofit in the U.S. dedicated to funding and accelerating biomedical research in the autism spectrum disorders.

All donations, large and small, help us to meet the NLM Challenge! If you are interested in making a significant gift or pledge, please contact Karen London, VP for Development, at 1-888-777-*NAAR*
or ***do it right now...*** by making a
Secure On-Line Donation.

- Find out more about ways to give to *NAAR*
- Autism Tissue Program Donor Registration
- Opportunities for Volunteer Service

For further information on *NAAR* and opportunities to contribute to its work contact the *NAAR* office at:

National Alliance for Autism Research	**(609) 430-9160; 888-777-*NAAR***
99 Wall St., Research Park	**(609) 430-9163 (fax)**
Princeton, New Jersey 08540	**naar@naar.org**

NAAR is a 501(c)(3) organization, contributions to which are tax-deductible as permitted by law. *NAAR* 's most recent financial statements are available online.

National Alliance for Autism Research

Background courtesy of the Background Boutique
--updated 02-Sept-01

Mr. BURTON. Are any of the minority members going to be here?

[No response.]

Mr. BURTON. We will now ask the first panel to come forward. Mr. Grossman, Ms. Lerner, Mr. Shore, and Mr. Compton, would you please approach the witness table and stand up so we can swear you in?

[Witnesses sworn.]

Mr. BURTON. Be seated.

We will start with you, Mr. Grossman. I guess we will just go right down the line. Do you have an opening statement?

STATEMENTS OF LEE GROSSMAN, PRESIDENT, AUTISM SOCIETY OF AMERICA, AND AN AUTISM PARENT, HONOLULU, HI; BELINDA LERNER, MEMBER, AUTISM COALITION, AND AN AUTISM PARENT, NEW YORK, NY; STEPHEN SHORE, BOARD MEMBER, UNLOCKING AUTISM, BROOKLINE, MA; AND DOUG COMPTON, SCIENTIFIC DIRECTOR, CURE AUTISM NOW FOUNDATION, NEW JERSEY

Mr. GROSSMAN. Yes, I do, Mr. Chairman.

Mr. BURTON. If we could, we would like to try to keep our opening statements to 5 minutes, if we can, so we can get through everybody and have time for questions.

Mr. GROSSMAN. Good afternoon. My name is Lee Grossman and I am president of the Autism Society of America, chair of the Autism Society of America Foundation, a member of the Federal Government's Interagency Autism Coordinating Committee, a resident of Honolulu, HI, a small business owner for over 20 years in the medical industry, and, most importantly, a father of a child with autism whose name is Vance.

Mr. Chairman, I would like to thank you and your colleagues on the Committee on Government Reform for this opportunity to present testimony on the issue of autism, the fastest-growing disability in our country today. As President of the Autism Society of America, I can tell you that hearings such as this offer hope to hundreds of thousands of individuals and families affected by autism.

I am going to deviate from my testimony a little bit to respond to your opening statements. They're very moving to me in that it truly represents what all of the families are going through, our experiences, our frustrations in dealing with this dilemma that we're faced with.

I want to thank you very much for acknowledging for the first time, that I am aware of, that the Federal Government is now acknowledging in this country that autism is an emergency, and it is a national health crisis. It is something that has not evaded the advocates and the families to this point. It is reassuring to all of us to know that the government is finally recognizing this as an epidemic.

There are a number of factors and figures that I would like to present here before I get into what I believe that we need to do and what ASA believes that we should do to correct this problem over the near short-term. Currently, it is easy to say that this is a national health crisis. There are as few as a half million to perhaps 1.5 million people with autism in the United States today. Estimates are as high as for every 1,000 children that are born today 6 will have autism.

The annual cost of treating autism in the United States is anywhere from $20 billion to $60 billion every year. Autism is growing at a rate of 10 to 17 percent each year. Based on these figures, in 10 years the annual costs associated with autism could be as much as $50 to $300 billion per year. After 60 years of dealing with this problem, the Federal Government is currently spending $75 million on research when the problem is in actuality conservatively a $20 billion problem. After 60 years of this approach, we have no identified causes of autism or any proven treatments or therapies. Something substantially greater has to be done to address this national emergency, and we have to spend substantially more money to find causes and effective treatments.

The Autism Society of America believes there are four critical areas that need to be addressed, and these four areas are in autism research, early identification intervention, secondary school education, and adult issues. Here are our immediate recommendations.

Current funding levels in biomedical research at NIH are terribly low in relation to the disorders population and economic impact. We are recommending that the Federal Government increase the funding available for research over the next 3 years to a level of $500 million per year devoted to basic science, environmental science, tissue and genetic collection, and all aspects of biomedical research related to autism. When compared to the annual growing rate of autism in our Nation, this is substantially below the funding to keep pace with the projected growth.

In the area of applied science, we must find new and innovative ways to develop and implement therapeutic and clinic interventions and effective treatments. There has been to date virtually no activity and support from Federal agencies in these vital areas. We recommend that applied research funding be increased over the next 5 years to a level of $100 million per year. This increase is needed in the case of autism because we are building from a zero base.

ASA also recommends that there is a need to increase the number of scientists involved with research and treatment grants. We request that NIH develop programs and encourage researchers to enter into fields associated with autism research and to stimulate new research protocols.

The CDC surveillance programs need to be implemented and then expanded immediately so that more exact figures on the prevalence and population of those with autism are established. In our discussions with CDC, we recognize that data from a substantial number of State or other geographic areas will be needed to better identify those who have autism and what scope of services will be needed. We, therefore, recommend that the CDC budget in this area be increased to $8 million to expand the number of regional centers and State surveillance programs from 9 States to 20 States. These 20 States should represent a statistically significant data base to allow CDC to better identify those who have autism, and then start looking for root causes and trends.

As we must find the causes and best treatments for those with autism, there is also a need to fund areas which could identify possible causes of autism created by our society. A substantial number of families within our autism community believe some forms of autism may be caused by some use of vaccines. While we do not know this to be specifically proved at this time, we should not ignore the body of evidence that calls into question the source of many children with autism. If causation is found, those injured must be provided recourse and compensation.

This is why ASA supports and asks for early adoption by Congress of the Burton-Waxman bill, H.R. 3741, which improves the National Vaccine Injury Compensation Program by extending the statute of limitations for individuals to file claims and provides a 2-year look-back provision for the families that are presently prevented from filing under the program, through no fault of their own.

Now under early diagnosis and early intervention, ASA strongly supports the general consensus that the most effective means for a successful result in the life of an individual with autism is through early diagnosis and early intense and appropriate intervention. Therefore, we recommend that a national awareness campaign be established through the U.S. Department of Health and Human Services, national physician organizations, and community health centers to provide education and identification programs to pediatricians, child care providers, and to the population at large.

ASA has expressed its willingness to act in concert with the Department to make this happen by drawing upon its unique membership and chapter base with the entire autism community. ASA also seeks increased funds for States to Early Head Start, or zero to 3, programs administered by the Administration for Children and Families to provide.

For education for children with autism, ASA recommends to the committee that it supports and develops legislation to implement the recommendations and plans detailed in the National Research Council's report, "Educating Children with Autism." This report precisely addresses the education interventional needs of secondary school age children with autism.

ASA further recommends that Congress immediately reauthorize the Individuals with Disabilities Education Act and fulfills the long overdue commitment to the full funding of IDEA, and, last, support services for adults with autism. The current availability of services, support, employment, and residential options available to adults with autism can only be described as almost non-existent. For too long the service supports for these people has dramatically dropped once the person passes through the secondary education system. A comprehensive program must be developed and implemented to address the tremendous needs of this growing and immense population.

ASA has developed a white paper on this subject and has posted it on our Web site to help develop interest in having it implemented. We have also joined with coalitions and formed coalitions of adult service providers, and are now doing assessments of the needs of the adults with autism community to formulate initiatives and legislation to address this problem. We ask the Congress and this committee to join in supporting the development of legislation and funding that will be necessary to deal with this current and ever-growing dilemma.

In closing, Mr. Chairman, I would be terribly remiss if I did not address the relevance and significance of this hearing. As I stated, this is the first time that I am aware of that the U.S. Government has acknowledged the autism epidemic and attendant national health crisis. And with your acknowledgment, ASA stands firm and ardent in requesting that this Nation take real and measurable actions today to stop this national economic, social, and health emergency.

I have described in my testimony what needs to be done now in terms of money and autism. However, there is something just as important to be added; that is hope. The autism community has endured 60 years of unfulfilled hope.

Congressman Burton, I know you have waited with hope for your grandson over the last 5 years. I have waited and hoped for the last 14 years, and the community has waited 60 years. If we will take the actions I have offered to you today, all of our hopes can be translated into fulfillment. Please let us help each other give meaningful hope to the millions of people affected by autism.

Thank you, Mr. Chairman, and I will stand ready to answer any questions you may have.

[The prepared statement of Mr. Grossman follows:]

Written Testimony
Before the

U.S. House of Representatives
Committee on Government Reform

Hearing on Autism

Room 2154
Rayburn House Office Building

April 18, 2002
1:00 p.m.

Lee Grossman

President
Autism Society of America

7910 Woodmont Avenue, Suite 300
Bethesda, MD 20814-3067
Tel: 301-657-0881
Fax: 301-657-0869
Web site: www.autism-society.org

My name is Lee Grossman and I am President of the Autism Society of America, Chair of the Autism Society of America Foundation, a member of the federal government's Interagency Autism Coordinating Committee, a resident of Honolulu Hawaii, a small business owner for over 20 years in the medical industry and, most importantly, a father of a child with autism, Vance. Mr. Chairman, I would like to thank you and your colleagues on the Committee on Government Reform for this opportunity to present testimony on the issue of autism, the fastest-growing disability in our country today. As president of the Autism Society of America, I can tell you that hearings such as this offer hope to the hundreds of thousands of individuals and families affected by autism.

The Autism Society of America (ASA) is the nation's largest autism organization with over 200 chapters throughout the U.S. representing professionals, individuals with autism, and their families.

I am here today to share some important information about autism with you and to tell you why it is imperative that we do everything possible to expand programs and research into this puzzling and debilitating disability. You may be surprised to learn that it has been 60 years since autism was first identified, and yet we still don't know what causes it, we don't know how to effectively treat it, and we don't know why it is on the rise although several theories exist regarding the dramatic increases that we are seeing across the United States.

Just ten (10) years ago, autism was thought to be a rare disorder affecting 1 in 10,000 individuals. Five years ago, researchers, including those at the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the Department of Education, estimated that 1 in 500 individuals had autism. Today, researchers believe this number may be closer to 3 in 500 (CDC, 2001). This means that as many as 1,500,00 individuals in this country alone may have autism today.

And, again, this number is on the rise and not solely due to better diagnosis and identification. Based on reports from the U.S. Department of Education and state agencies, the ASA estimates that autism is increasing at a the alarming rate of 10 to 17 percent each year, faster than any other disability or disease. At these rates, in the next decade, autism could surpass mental retardation as the most common developmental disability facing this country.

If we don't act now, there is no doubt that autism will have devastating effects on our national health and education systems. Today, the total cost of autism is $20 billion to $60 billion annually (based on current figures of 500,000 to 1,500,000 individuals with autism at an annualized per-person cost of $40,000). By 2010, this cost associated with autism could more than double or quadruple to $55 billion to $300 billion per year.

The only way to prevent this economic fallout from becoming a reality is to invest more money in research to solve the puzzle of autism, to expand educational and vocational opportunities, and to create support services that are currently lacking or non-existent for those already affected by autism.

Research and programs are needed now if we are to thwart the growth rate and to prevent more families from receiving the devastating news that their son or daughter has autism. We commend you and your committee for your recognition of the growing problem of autism with strides you have made in the last two to three years to raise awareness about autism and to support and put into motion several research initiatives and funding, including the research programs established as a result of the Children's Health Act of 2000. This is the type of informed action of which I speak.

In fiscal year 2002, NIH will be spending $66 million on autism activities, the CDC through its Center for Birth Defects and Developmental Disabilities will be allocating $9,230,000 for its surveillance programs. These funding levels represent a dramatic increase in research towards this disorder. We applaud the work of those federal agencies, which the ASA has enjoyed a close relationship with.

Unfortunately, these gains pall compared to the huge economic and social problem of autism today and in the near future. Our nation is in the grasp of an autism national emergency health crisis; a crisis that demands a significantly more aggressive response from the federal government to counter the growing costs and fractured lives caused by autism. If we are going to make further progress in our understanding of this disability and begin making strides in treating it, we must geometrically increase the research commitment from all areas of the federal government to approach the geometric growth of autism.

The ASA is the voice of the autism community, and that community seeks increased funding for: 1) research and prevalence studies, 2) physician and caregiver awareness programs, and 3) early intervention programs. The ASA also calls for legislative action with regard to the recommendations of the National Research Council's report "Educating Children with Autism" and the need for support services for adults with autism. Please note that as long as the cause and cure for autism elude us, more and more persons with autism will become adults with autism. The appropriate care levels for adults are and will be greater than costs related to children.

Autism Research

Current funding levels in biomedical research at NIH are terribly low in relation to the disorder's population and economic impact. We are recommending that the federal government increase the funding available for research over the next three years to a level of $500 million per year devoted to basic science, environmental science, tissue and genetic collection, and all aspects of biomedical research related to autism. When compared to the annual growing rate of autism in our nation, this is substantially below funding to keep pace with the projected growth of autism.

In the area of applied research, we must find new and innovate ways to develop and implement therapeutic and clinical interventions and effective treatments. There have been to date virtually no activity and support from federal agencies in these vital areas. We recommend applied research funding be increased over the next five years to a level of $100,000,000 per year. This increase is needed in the case of autism because we are building from a zero base.

ASA also recommends that there is a need to increase the number of scientists involved with research and treatment grants. We request that NIH develop programs that encourage researchers to enter into fields associated with autism research and to stimulate new research protocols.

The CDC surveillance programs need to be implemented and then expanded immediately so that more exact figures on the prevalence and population of those with autism are established. In our discussions with CDC, we recognize that data from a substantial number of state or other geographic areas will be needed to better identify those who have autism and what scope of services will be needed. We, therefore, recommend that the CDC budget in the area be increased by $8 million to expand the number of regional centers and state surveillance programs from nine states to twenty states. These twenty states should represent a statistically sufficient database to allow CDC to better identify those who have autism, and then start looking for root causes and trends.

As we must find the causes and best treatments for those with autism, there is also a need to fund areas which could identify possible causes of autism created by our society. A substantial number of families within our autism community believe some forms of autism may be cause by some use of vaccines. While we do not know this to be specifically proved at this time, we should not ignore the body of evidence which calls into question the source of many children with autism. If causation is found, those injured must be provided recourse and compensation. This is why ASA supports and asked for early adoption by the Congress of the Burton-Waxman Bill (HR 3741) which improves the National Vaccine Injury Compensation Program by extending the statute of limitations for individuals to file claims and provides a two (2) year "Lookback provision" for the families that are presently prevented from filing under the program through no fault of their own.

Early Diagnosis and Early Intervention for Children with Autism

ASA strongly supports the general consensus that the most effective means for a successful result in the life of an individual with autism is through early diagnosis and early, intense, and appropriate intervention. Successful early diagnosis and intervention is a proven way to reduce the huge social and economic burden of autism.

Therefore, we recommend that a national awareness campaign be established through the U.S. Department of Health and Human Services (DHHS), national physician organizations, and community health centers to provide education and identification programs to pediatricians, child care providers and to the population at large. ASA has expressed its willingness to act in concert with DHHS to make this happen by drawing upon its unique membership and chapter bases with the entire autism community.

ASA also seeks increased fund for states through their Early Head Start (0-3) programs administered by the Administration for Children and Families to provide the intensive interventions that are necessary to provide effective treatments to these children with autism.

Education for Children with Autism

ASA recommends to the Committee that it support and develop legislation to implement the recommendations and plan detailed in the National Research Council's report "Educating Children with Autism." The report precisely addresses the educational and intervention needs of secondary school aged children with autism. This is a case where the outreach of ASA has confirmed that there is something already in existence that can work today to benefit those with autism. This means money need not be spent on creating something new, but funds should be provided to get out the messages in this document and get what it advocates, which will be supported by the ASA, into practice.

ASA further recommends that Congress immediately reauthorize the Individuals with Disabilities Education Act (IDEA) and fulfills the long overdue commitment to the full funding of IDEA so our children and loved ones will be able to obtain a free and appropriate education.

Support and Services for Adults with Autism

The current availability of service, support, employment and residential options available to adults with autism can only be described as almost non-existent. For too long the service supports for these people has dramatically dropped once the person passes through the secondary education system. A comprehensive program must be developed and implemented to address the tremendous needs of this growing and immense population.

ASA has developed a white paper on this subject and has posted it on our Web site to help develop interest in having it implemented. ASA has joined with a coalition of adult service providers, and is assessing the needs of adults with autism to formulate initiatives and legislation to address this problem. We ask the Committee to join us in supporting the development of legislation and funding that will be necessary to deal with this current and ever-growing dilemma.

Conclusion

In closing, Mr. Chairman, I would be remiss if I did not address the relevance and significance of this hearing. It is the first time that I am aware that the United States government has acknowledged the Autism Epidemic and attendant national health crisis. And with your acknowledgement, ASA stands firm and ardent in requesting that this nation take real and measurable actions today to stop this national economic, social and health emergency.

I have described in my testimony what needs to be done now in terms of money and autism. However, there is something just as important to be added -- that is hope. The autism community has endured 60 years of unfulfilled hope.

Congressman Burton, I know you have waited with hope for five years, and I have waited and hoped for 14 years. If we will take the actions I have offered to you today, all our hopes can be translated into fulfillment. Please let us help each other give meaningful hope to the millions of people affected by autism. Let's take action!

Mr. BURTON. Thank you for that statement, Mr. Grossman. Your recommendations, along with the others that we will hear today, will be given to the officials at NIH and CDC and the FDA. We have some of them here who are going to be testifying in a little bit, and they are, I am sure, taking all this in.

Ms. Lerner.

Ms. LERNER. Thank you, Chairman Burton and distinguished members of the committee.

I am here to speak to you today about my personal experiences with the heartbreak and frustrations of autism. By way of history, you should know, and as Chairman Burton has already said, that professionally I am an attorney with the National Football League. My job has presented me with many interesting challenges, including cross examining 6-foot 5-inch, 300-plus pound professional football players. I was the first female attorney hired in that role, and so my challenges were not limited to my interactions with football players, but in winning the confidence and respect of my male colleagues in the league and at the NFL clubs. However, those challenges, while daunting at the time, pale in comparison to the challenges I have faced, and continue to face, as a mother of an autistic son.

My son, Benjamin, was diagnosed when he was 2 years old, and when I received the news, I was relieved—yes, relieved. Prior to his diagnosis, I was the mother of a screaming, inconsolable, non-communicative little boy, who seemed to reject all my attempts to love him and was incapable of demonstrating his love for me. At a time when I should have been awash in feelings of love, I was overwhelmed by feelings of inadequacy, failure, and shame.

Now the enemy that had overtaken my son had a name—autism—and like any lawyer worth her salt, I was going to defeat my adversary by researching and understanding its characteristics. I remember bombarding the psychologist, who had diagnosed Ben, with questions: What causes autism? No one knows. How prevalent is it? Undetermined, last count, 1 in 500. What treatments are most effective? It is unclear. There have been no reliable studies. Most importantly, what are my son's chances for a normal life? Hard to say, but not particularly good.

I refused to be cowed, but little did I know at the time the journey I was embarking on. I was able to secure a spot for Ben in a wonderful school dedicated to children with developmental disorders, where by the age of 3 he began to master basic language and other life skills. Finally, the wonderful, charming little boy hidden beneath the disorder began to emerge, and so did this incredible bond between Ben and me.

Although Ben was making progress, he, nonetheless, still had substantial and pervasive deficits. And so each time a new problem arose that required additional therapy, we needed to get permission from the school district's Committee on Pre-School Education to amend his individual education plan [IEP], to address this problem. Although I had my share of battles with the CPSE to get appropriate services for Ben, it wasn't until Ben turned 5 and was transitioned from the CPSE to the CSE, Committee on Special Education, that the hostilities elevated to an all-out war.

At that point Ben was to graduate from his special education school. So my husband and I evaluated the school district's inclusion kindergarten program, and we both agreed that the curriculum and behavioral requirements were far too advanced for Ben at that time. However, the school district refused to provide us with any alternatives. So even though the law requires that a "free and appropriate education in the least restrictive environment" be provided to each child, we were left with the choice of putting him in the school district's program or pay out of pocket for any alternative.

We knew that following the district's mandate would be setting Ben up for failure, in our experience a sure-fire recipe for disaster and regression. If we sued the school district, it would cost us as much as a year's tuition. So we bit the bullet and sent Ben to a private pre-kindergarten program at our expense.

This private school was initially a godsend for us, and Ben continued to make small, but steady progress. But as Ben went from pre-K to the typical kindergarten program, it was clear that his developmental problems were too severe to be handled by a well-intentioned but untrained and underequipped staff.

Because the school district would not provide additional support for Ben at his private school, his failure to get the appropriate interventions resulted in his lashing out and shutting down. Once again, the shadow of autism was eclipsing my sweet, charming little boy who had been showing so much promise.

My husband and I pulled Ben from the private school, obtained additional therapy and additional evaluations at our own expense, and put him in our only other alternative, the school district's kindergarten program, which we had rejected 2 years earlier. Ben is no longer regressing, but he is still significantly delayed in all developmental categories.

Our most recent round of evaluations have revealed that, unless Ben receives intensive interventions this summer to make up for the losses he experienced this school year, he has absolutely no chance of surviving first grade. However, because the CSE has refused to classify Ben as a child who needs year-round services, the job of securing the right therapists, as well as the financial burden of providing them, will fall to us.

Based on my unwavering love for my little boy, I am determined to do what is in his best interest so that he may have a chance for a happy, independent life. However, I and similarly situated parents are faced with many obstacles, and it is time for the Federal Government to share the burden and the shame that has dogged the parents of the autistic, and the lack of government assistance in autism to date is shameful. It is shameful that this country, the greatest nation in the world, has conducted no concerted nationwide prevalence study.

Funding Centers of Excellence, pursuant to the Children's Health Care Act, would give us a vehicle to conduct a proper nationwide tracking program. It is shameful that there has not been significant funding into biomedical research. Less than two generations ago, the disorder was thought to be a mental illness caused by cold and detached mothers. Although we now know it is a neurological disorder, we have yet to determine what causes the autism and how it impairs the brain's functioning.

It is shameful that this country has not conducted meaningful and concerted applied research to determine what therapies are most effective in countering the horrific effects of autism. Our schools have been besieged by this growing population, and while required by law to educate and treat the autistic, they lack funding and training to handle this enormous responsibility. Fully funding the IDEA statute would alleviate some of that burden.

Finally, it is shameful that our Nation, either through willful ignorance or benign neglect, has allowed this insidious and pervasive health care crisis to rise to epidemic proportions.

I began my testimony by presenting to you the challenges I have faced professionally and personally as a mother of an autistic son, and I would like to conclude by asking that you adopt these challenges and support the funding for the five Centers of Excellence and IDEA. Past generations were damned to institutionalization. Let's not condemn our present and future generations to the same fate.

I speak on behalf of the exhausted, voiceless, and desperate parents of autistic children, the children that without the proper government intervention will become adults doomed to be a financial burden rather than a contributing member of society. So please give full force and effect to the Children's Healthcare Act and the IDEA statute. Thank you.

[The prepared statement of Ms. Lerner follows:]

COMMITTEE ON GOVERNMENT REFORM
APRIL 18, 2002
BELINDA LERNER

Chairman Burton and distinguished members of the Committee thank you for inviting me.

I am here to speak to you today about my personal experiences with the heartbreak and frustrations of autism. By way of history you should know that professionally I am an attorney with the National Football League. My job has presented me with many interesting challenges, including cross-examining six foot five inch, 300+ pound professional football players. I was the first female attorney hired in that role and so my challenges were not limited to my interactions with football players, but in winning the confidence and respect of my male colleagues in the League and at the NFL clubs. However, those challenges, while daunting at the time, pale in comparison to the challenges I have faced and continue to face as a mother of an autistic son.

My son, Benjamin, was diagnosed when he was two years old and when I received the news I was relieved --yes relieved. Prior to his diagnosis I was the mother of a screaming, inconsolable, non-communicative little boy, who seemed to reject all my attempts to love him and was incapable of demonstrating his love for me. At a time when I should have been awash in feelings of love, I was overwhelmed by feelings of inadequacy, failure and shame.

Now the enemy that had overtaken my son had a name -- autism -- and like any lawyer worth her salt I was going to defeat my adversary by researching and understanding its characteristics. In retrospect, a very naïve approach. I remember bombarding the psychologist, who had diagnosed Ben, with questions.

- What causes autism? No one knows.
- How prevalent is it? Undetermined, last count it was 1 in 500.
- What treatments are most effective? It's unclear. There have been no meaningful or reliable studies.
- Most importantly, what are my son's chances for a normal life? Hard to say, but not particularly good.

I refused to be cowed, but little did I know at the time the journey I was embarking on.

I was able to secure a spot for Ben in a wonderful school dedicated to children with developmental disorders, where by the age of three he began to master basic language and other life skills. Finally, the wonderful, charming little boy hidden beneath the disorder began to emerge and so did this incredible bond between Ben and me. Although Ben was making progress, he nonetheless still had substantial deficits cognitively, in communication and in socialization. And so each time a new problem arose that required additional therapy, we needed to get permission from the school district's Committee on Pre-School Education to amend his Individual Education Plan or IEP to address the problem. Although I had my share of battles with the CPSE to get the appropriate services for Ben, it wasn't until Ben turned five and was transitioned from CPSE to the CSE, Committee on Special Education, that the hostilities elevated to an all out war.

At that point Ben was to graduate from his special education school, so my husband and I evaluated the school district's inclusion kindergarten program and we both agreed that the curriculum and behavioral requirements were far too advanced for Ben at that time. However, the school district refused to provide us with any alternatives. So even though the law requires that a "free and appropriate education in the least restrictive environment" be provided to each child, we were left with the choice of putting him in the school district's inclusion kindergarten program or pay out of pocket for any alternative. We knew that following the districts mandate would be setting Ben up for failure, in our experience a sure fire recipe for disaster and regression. If we sued the school district, it would cost us as much as a year's tuition. So we bit the bullet and sent Ben to a private Pre-kindergarten program at our expense. This private school was initially a godsend for us, and Ben continued to make small, but steady progress. But as Ben went from pre-K to the typical kindergarten program, which introduced academics, it was clear that his developmental problems were too severe to be handle by a well-intentioned but untrained and under equipped staff. Because the school district would not provide additional support for Ben at his private school, his failure to get the appropriate interventions resulted in his lashing out and shutting down. Once again, the shadow of autism was eclipsing my sweet, charming little boy that had been showing so much promise.

My husband and I pulled Ben from the private school, obtained additional therapy and additional evaluations at our own expense and put him in our only other alternative the school district's kindergarten program, which we had rejected two years earlier. The school staff has been very cooperative in working with us to help Ben so that he is no longer regressing, but he is still significantly delayed in all developmental categories. Our most recent round of evaluations have revealed that unless Ben receives intensive interventions this summer to make up for the losses he experienced this school year he has absolutely no chance of surviving first grade. However, because the CSE has refused to classify Ben as a child who need year-round services, that means that securing the right therapists as well as the financial burden of providing him with most of his treatments falls on us.

Based on my unwavering love for my little boy, I am determined to do what is in his best interest so that he may have a chance for a happy, independent life. However, I and similarly situated parents are faced with many obstacles.

1. Since what causes or contributes to autism is unknown parents embark on an endless odyssey to try and determine what environmental or dietary triggers may cure or improve their child's symptoms; and to compound that problem.

2. Since there are no statistics on best remediation practices, we rely on anecdotal evidence to determine what interventions have had the most success.

It's time for the federal government to share the burden and the shame that has dogged the parent's of the autistic. And the lack of government assistance in autism to date is shameful.

1. It is shameful that this country, the greatest nation in the world, has conducted no concerted, nation-wide prevalence study. I have read statistics indicating autism diagnosis has increased 600% in the last six years and that in California there is a child diagnosed with autism every four hours, twenty-four hours a day, seven days a week. Yet, when I read the CDC's website, a government entity, it unabashedly admits that "it is not known how many children in the United States currently have autism spectrum disorders". Funding "Centers of Excellence" pursuant to the Children's Health Care Act would give us a vehicle to conduct a proper, nation-wide tracking program.

2. It is shameful that there has not been significant funding into biomedical research. Less than two generations ago, the disorder was thought to be a mental illness caused by cold and detached mothers. Although we now know it is a neurological disorder, we have yet to determine what causes the autism and how it impairs the brain's functioning. For far too long, autism had been neglected by federal health, medical and research programs.

3. It is shameful that this country has not conducted meaningful and concerted research on what therapies are most effective in countering the horrific effects of autism. It has been documented that early and intensive intervention is the only hope for the autistic, yet we have yet to determine what therapies are most effective. Parents are left to trial and error approaches in getting their children help, which results in tremendous waste of valuable time and money. Our schools have been besieged by this growing population and while required by law to educate the autistic they lack the funding and the training to handle this enormous responsibility. Fully funding the IDEA statute would alleviate some of their burden.

4. Finally, it is shameful that our nation either through willful ignorance or benign neglect has allowed this insidious and pervasive healthcare crisis to rise to epidemic proportions.

I began my testimony by presenting to you the challenges I have faced professionally and personally as a mother of an autistic son and I would like to conclude by asking that you adopt these challenges and support the funding for research and awareness into autism. Past generations were damned to institutionalization; lets not condemn our present and future generations to the same fate. I am here to speak on behalf of the exhausted, voiceless and desperate parents of autistic children. Seventy-five percent (75 %) of those diagnosed with autism are between 3-13 years of age. These children will soon become adults and without the proper government intervention, adults that will miss their opportunity to become contributing members of society and instead become a financial burden on society. For our sake and for the sake of this country's future please help give our children a chance to realize their potential by giving full force and effect to the Children's Healthcare Act and the IDEA statute.

Mr. BURTON. Thank you for that statement. I would urge all of you who are interested and who are leaders in the autistic community to write your Congressmen and to write the White House and to tell them that you want these changes made and that there be appropriate funding for all of these research programs that you talked about, because the squeaky wheel in this town gets the oil.

You talk about the AIDS research, and I am taking a little liberty here, so forgive me. The AIDS research moneys that are being spent are huge. I don't fault them for giving that money to AIDS research. I think it is important. But autism is equally important. Because they have been very outspoken in the AIDS community, they have gotten a great deal of results from the health officials of this country, and from the Congress, and from the administrations, $700 million; I believe it was pretty close to that. If we had that kind of money being given for autism research, we could probably get a lot more accomplished.

So write your Congressmen. Don't write me. I am already on board. [Laughter.]

But write your Congressman and write the White House and Senators and tell them that you want something done.

Dr. WELDON. Mr. Chairman.

Mr. BURTON. Yes?

Dr. WELDON. Could you yield to me on this issue?

Mr. BURTON. I will be glad to yield.

Dr. WELDON. Just for a minute?

Mr. BURTON. Sure.

Dr. WELDON. I was going to say this in my question period. If you add up—comparing to AIDS is a good thing because the prevalence is somewhat similar. It is estimated 500,000 to a million with autism and there's 500,000 people with AIDS, about 900,000 if you add AIDS and HIV-positive status.

If you add up the money that is spent by NIH, CDC, Medicare, Medicaid, the housing money, the drug money, the Federal Government is spending $12 billion on AIDS. That is why I refer to this as a forgotten disease. You know, Mr. Grossman, you laid out a really nice strategy. I mean it was great. I was really glad to hear you do all that.

You've got a bunch of people here that are going to be foursquare behind you, but you have got to develop a very sophisticated lobbying effort. You are a 600-pound gorilla that has been asleep for years. I can tell you, if you get your act together and start working this town aggressively—and you ought to meet with the AIDS people and just have them brief you on how they did it. I mean, we are going to double the NIH budget, and everybody is going to be out there to take a piece of it: the kidney people, the heart people, the Parkinson's people. But they've already got a big chunk, and the time is really ripe. I apologize for rambling on here.

Mr. BURTON. No, that is all right.

Dr. WELDON. You brought it up, Mr. Chairman.

Mr. BURTON. It adds to the discussion.

Dr. WELDON. It is a two-way street. You know, you've got to work this town, and you've got to be really slick and really sophisticated, and you've got to put money into it, too. There are a lot of people, NFL football players, businessmen with money who will write checks, and you've got to hire consultants. You've got to do a whole 9 yards, but you ought to do it because I think you can cure autism. I really do.

Mr. BURTON. Thank you, Dr. Weldon.

Mr. Shore.

Mr. SHORE. Chairman Burton, I thank you and your colleagues on the Committee on Government Reform for this opportunity to present testimony, this historic opportunity to present testimony on the issue of autism.

I am Stephen Shore and reside in Brookline, MA with my wife Leawee, where I am completing a doctoral degree in special education from Boston University with an emphasis on helping those with autism reach their fullest potential. I am the author of "Beyond the Wall: Personal Experiences with Autism and Asperger's Syndrome," consult internationally for autism-related issues, teach college-level courses in special education at both Boston University and Lesley University, as well as work with people that have autism. I am very fortunate to be leading a fulfilling and productive life.

Most of us here today have involuntarily been inducted into this community by the autism bug. What happens? A child is born and develops typically until 18 to 24 months, suddenly hit with a bomb that spreads its shrapnel from the child to the family, to education, the community, and humanity at large. The child loses verbal ability; withdrawal from the environment occurs. We often see self-abusive and self-stimulatory behaviors, tantrums.

I was hit with that very same bomb at age 18 months with all those wonderful characteristics that we see going with it. Despite the claim of being too sick to work with and recommendations for institutionalization by diagnosing professionals, it was my parents that were left to provide the needed early intervention, and this was at a time when that term had yet to be conceived. We are talking about the early mid-sixties. My parents had no support.

However, fortunately, my mother was able to stay home all day and provide the equivalent of what is known today, or would be known today, as a home-based early intervention with an emphasis on music, movement, sensory integration, narration, and imitation—to at first make me aware of her presence, and then to coax me out into her world. I was very lucky. Parents and educators, we need to listen to the parents. They are the experts on their children.

At this time I am before you as I continue my quest to help those with autism and Asperger's disorder lead fulfilling and productive lives. I continue to struggle with the residuals of autism. While the uniform of a suit and tie that we find in government and business may be a mere inconvenience to most people, it is a major sensory violation for me. However, helping my peers on the autism spectrum is way more important than my discomfort.

I am very lucky and the rare exception of a child with an early autism spectrum diagnosis. Here in the United States of America, the wealthiest, most powerful Nation on Earth, everyone on the autism spectrum has a right under IDEA to receive critical services throughout their lifespan tailored to their needs. This should not be a matter of luck or debate, but it is a question of how.

These are some of my observations. As board president of the Asperger's Association of New England, board member of the Autism Society of America, Unlocking Autism, and other national autism-related organizations, I see many others with autism spectrum disorder who are vastly underserved: toddlers not receiving vitally needed early intervention and school age children in need of professionals educated in how to interact with those on the autism spectrum.

We desperately need more educational research. Today we know very little about the interventions that are effective with individuals with high-functioning autism and Asperger's syndrome. The implications are enormous. So many of my peers living far below their potential, homelessness, other substandard living conditions, unemployment, and serious underemployment are all too common.

People with high-functioning autism and Asperger's syndrome need to be taught more how to interact successfully with the environment and people around them. Until medical terminology can answer the questions it is pursuing, we have thousands of individuals who are exposed to educational interventions that are not validated or, perhaps even more tragic, not exposed at all because the educational community doesn't know what to do.

We have some literature that supports best practice for people with moderate to severe autism spectrum disorders, but the same cannot be said for individuals with high-functioning autism and Asperger's syndrome. We need to look at the academic, cognitive, developmental, behavioral, social, sensory, and other interventions.

As was mentioned before, the CDC estimates that 1 out of 250 children have autism right now. What are we going to do in 10 to 15 years when they become adults? This number, 1 in 250, is actually much greater if we look at the people that are affected by autism. What do I mean by that? We are talking about the family. One child has autism. We have other siblings. We have parents, grandparents, other relations, friends. Funds devoted to research and early intervention now will pay huge dividends later.

But what about the adults? There is very little literature on this population also. What happens in the Commonwealth of Massachusetts where I live is we see people with high-functioning autism not being served by the Department of Mental Retardation because they have an IQ over 70; thus, they are not considered as having retardation. The Department of Mental Health says autism is not a psychiatric disorder, so they don't get services from the Department of Mental Health. As a result, they fall in the crack, a big crack, and don't receive services at all, and similar situations exist in many other States also.

What I have described, and what has been talked about by you, by Lee, by Ms. Lerner, is a national emergency. They were talking about up to 1.5 million individuals in the United States having autism, and the numbers are rising. The U.S. Department of Education, the California Department of Developmental Services, and others, ASA, estimates autism is growing at a rate of 10 to 17 percent annually. We are talking about a rate of 100 to 400 percent over the next 10 years.

If we look at the Mind Institute, they estimate that the conservative cost of a lifetime of care, and here we are talking only transportation, day services, and residential care, for every person with autism is $2 million. Multiply that by 1 million and 1.5 million, and that doesn't even begin to express the opportunity cost of lost wages and other contributions to society such as charitable work and even playing in musical ensembles. Every one of these persons must be given the same chance that only a select few, often due to luck, have had to succeed in life.

I would like to close with several concrete recommendations. One is let's work with the Autism Society of America by supporting their funding request and in developing legislation regarding the autism spectrum, including implementation of the National Research Council's Educating Children with Autism Report recommendations.

Two, immediate and abundant funding for research and education of those who work with people having autism.

Three, fund fellowships to increase the number of skilled medical doctors, teachers, and other professionals in working with people in the autism spectrum.

Four, mainstream autism as it relates to insurance payments. We are dealing with a medical neurobiological condition, and not a psychiatric one, and, thus, should not be constrained by policy limits that we see on mental health coverage.

Five, standardized payments for recognized methods of interventions across the country. It is unfair that some families are placed on long waiting lists, perhaps a year or two, to access coverage.

No one particular approach can be required because different children respond to different methodologies. According to IDEA, we have to provide the child what they need in order to get the education they need. Some sound approaches include, but are not limited to, the Miller Method, Floor Time, Hagashi, Teach, and applied behavioral analysis.

In summary, it is clear that we have some good interventions and treatments for autism in place at this time, but it is a travesty that the quantity and quality of these services are lacking. The NIH needs to work with organizations such as the Autism Society of America in developing national policy for people within the autism community, so that all those having autism have a fair shot at leading fulfilling, productive, and independent lives to the limits of their capacities.

Mr. Chairman and members of the Committee on Government Reform, your providing this historic opportunity to present testimony on this issue of autism today is very much appreciated. I know you will do the right thing. Thank you, and I am here to serve you.

[The prepared statement of Mr. Shore follows:]

Written Testimony
Before the

U.S. House of Representatives
Committee on Government Reform

Hearing on Autism

Room 2154
Rayburn House Office Building

April 18, 2002
1:00 p.m.

Stephen Shore

Member, Board of Directors
Autism Society of America

President, Board of Directors
Asperger's Association of New England

Board of Directors
Unlocking Autism

Member, Board of Directors
Asperger's Syndrome Coalition of the United States

Introduction

Mr. Chairman. I would like to thank you and your colleagues on the Committee on Government Reform for this opportunity to present testimony on the issue of autism.

I am Stephen Shore and reside in Brookline, Massachusetts with my wife Yi Liu where I am completing a doctoral degree in special education from Boston University with an emphasis on helping those with autism reach their fullest potential. I am the author of Beyond the Wall: Personal Experiences with Autism and Asperger Syndrome, present and consult internationally for autism-related issues, teach college-level courses in special education, and work with people on the autism spectrum. I am very fortunate to be leading a fulfilling and productive life.

Most of us here today have involuntarily been inducted into this community by the autism bomb. What happens? A child is born and develops typically until 18-24 months. Suddenly, hit with a bomb that spreads its shrapnel from the child, to the family, to education, the community, and humanity at large, the child loses verbal ability. Withdrawal from the environment occurs. There is often self-abusive and self-stimulatory behaviors. Tantrums.

I was hit with the autism bomb at age 18 months. Loss of verbal communication, lack of body to environmental relationship, tantrums, head banging, self-stimulatory behaviors. Despite a claim being "too sick" to work with and recommendations for institutionalization by diagnosing professionals, my parents were left to provide the needed early intervention at a time when the term had yet to be conceived. My parents had no support. Yet fortunately, my mother was able to stay home all day and provide the equivalent of what is known today as home-based early intervention. Rather than let me spend my time exhibiting autistic behaviors, my mother emphasized music, movement, sensory integration, narration, and imitation to at first make me aware of her existence, and then coax me into her world. I was very lucky.

At this time, I stand before you as I continue my quest to help those with autism spectrum disorder lead fulfilling and productive lives. I continue to struggle with the residuals of autism. While the uniform of a suit and tie may be a mere inconvenience to most people, it is a major sensory violation to me. But helping my peers on the autism spectrum is more important than my discomfort. I am very lucky and am the rare exception of a child with an early autism spectrum diagnosis.

Here, in the United States of America, currently the wealthiest nation on Earth, everyone on the autism spectrum has a right under IDEA to receive critical services throughout their lifespan tailored to their needs. This should not be a matter of luck or debate but a question of how.

Observations

What about those less fortunate children and adults who are not receiving needed intervention and assistance to successfully navigate their environment? As Board President of the Asperger's Association of New England, Board Member of the Autism Society of America, and board member of other national autism-related organizations, I see many others with Autism Spectrum Disorder (ASD) who are vastly underserved. Toddlers not receiving vitally needed early intervention and school-aged children in need of professionals educated in how to interact with those on the autism spectrum.

We desperately need more educational research. To date, we know very little about the interventions that are effective with individuals with high functioning autism and Asperger Syndrome. The implications of that are enormous. I see so many of my peers living far below their potential. Homelessness and other substandard living conditions, unemployment and serious underemployment are all too common. People with HFA and AS have not been taught to interact successfully with the environment and people around them.

Until medical technology can answer the questions it is pursuing, we have thousands of individuals who are exposed to educational interventions that are not validated or, perhaps even more tragic, not exposed to interventions because the educational community does not know what to do. There is some literature that supports best practice for children and youth with moderate to severe autism spectrum disorders, but the same cannot be said for individuals with high functioning autism and Asperger Syndrome. We need to look at academic, cognitive, developmental, behaviorial, social, sensory, and other interventions. Due to the vast diversity in people with autism, there is no one methodological approach that suits all children. The intervention must be tailored to fit the person's particular needs. If the CDC estimates one out of 250 kids have autism right now, they need to consider that in 10-15 years one out of 250 ADULTS will have autism, and then what will we do? Funds devoted to research and early intervention now will pay huge dividends later.

And what about adults with High Functioning Autism (HFA) and Asperger Syndrome (AS)?

We also need to look at the plight of adults with Asperger Syndrome and high functioning autism. There is very little literature on this population also. Generally adults with HFA and AS do not have access to community supports because of their IQ, but don't have the skills to live independently or to seek and/or keep jobs even though they have university degrees. In the commonwealth of Massachusetts, persons with high functioning autism and Asperger Syndrome fall in the cracks between the Department of Mental Retardation (IQ is too high) and Department of Mental Health (HFA and AS are not mental disorders). Similar situations exist in many other states too.

In addition, there is a large number of adults who want to access universities but need a myriad of supports to be successfully. We need a study of these individuals and supports needed relative to these three topics.

We also need more effort placed on teacher training so that those who educate children and youth with ASD understand ASD, can translate research to practice, and document child progress.

What I have described above is a national emergency. Between 2 and 6 per 1,000 individuals are estimated to have autism, according to the Centers for Disease Control and Prevention. This means that some 500,000 to 1,500,000 individuals in the U.S. have autism today, and the numbers are rising. Based on reports by the U.S. Department of Education, the California Department of Developmental Services, and others, ASA estimates autism is growing at a rate of 10 to 17 percent annually. If these rates continue, ASA estimates that the number of individuals with autism could increase by 100 to 400 percent over the next 10 years. According the MIND institute, the conservative cost of a lifetime of care (including only transportation, day services, and residential care) for every person with autism in California's developmental services system is $2 million according to the California Department of Developmental Services. That $2 million staggers the mind when multiplied by the number of individuals with autism in the U.S. And this raw dollar amount does not even begin to express the opportunity cost of lost wages and other contributions to society such as charitable work and playing in musical ensembles.

Every one of these persons must be given the same chance that only a select few due to luck have had to succeed in life.

Recommendations

I'd like to close with several concrete recommendations:

1. Work with the Autism Society of America by supporting their funding requests and in developing legislation regarding the autism spectrum as well as implementation of the National Research Council's "Educating Children with Autism" report recommendations.

2. Immediate and abundant funding for research and education of those who work with people having autism.

3. Fund fellowships to increase the number of skilled medical doctors, teachers, and other professionals in working with people on the autism spectrum.

4. Mainstream autism as it relates to insurance payments. It is a medical neurobiological condition (not a psychiatric one) and should not be constrained by policy limits on mental health coverage.

5. Standardize payments for recognized methods of interventions across the country. It is unfair that some families are on waiting lists for two years to access coverage. No one particular approach can be required because different children respond to different methodologies. Some sound approaches include but are not limited to the Miller Method, Floortime, Higashi, TEACCH, and ABA.

Summary:

While we do have some good interventions and treatments for autism in place at this time, it is a travesty that the quantity and quality of these services are lacking. The NIH needs to work with organizations such as the Autism Society of America in developing national policy for people within the autism community so that **all** those having autism have as fair a shot at leading fulfilling, productive, and independent lives to the limits of their capacities.

Mr. BURTON. Thank you, Mr. Shore. Mr. Compton.

Mr. COMPTON. Good afternoon, Chairman Burton and members of the committee. My name is Doug Compton, and I have been an advocate for the autism community for 6 years while I was a career scientist studying heart disease. I have recently become the science program director for the Cure Autism Now Foundation. My son, Daniel, who is now 9 years old, has autism.

I won't restate the prevalence estimates. As we all know, they are high, and scientists are debating why these numbers are changing, the extent to which the environmental factors are playing, whether diagnosis is playing a role in the rise, or whether genetics are playing a role in the rise with its interaction with environmental factors.

What I will say is that we still do have hope. Four years ago my family and I came from New Jersey to the Capital to help introduce the Children's Health Act. We came with enthusiasm, and it was a bright day. My son stood at a microphone such as this and repeated his favorite script over and over, and he is still doing that to this day.

During the years between the introduction of the bill and its passage, groups such as Cure Autism Now, the National Alliance for Autism Research, and the ASA formed partnerships to establish genetic resources, brain resources, and alliances with the NIH and other organizations studying autism. Together, we funded research to try to identify the causes from genetics to environment. We have funded brain imaging studies. We have funded animal models and treatment trials. We have closed no doors, as there is still no conclusive evidence as to what causes this thing we call autism, nor are there any universally effective treatments.

We continue to push the research agenda from the private sector, but we need our government to push harder. While there has been a large increase in funding from the Federal Government from $5 million to $30 million a year, this is far from sufficient. It is not commensurate with or ambitious enough to address the depth of the human suffering and of the economic hardship which the disorder is placing on affected individuals.

The formula by which specific funding is allocated by the NIH is a mystery to us. Far more money is spent on diseases, as you said, which affect fewer people. We understand that the NIH has to follow the scientific opportunity, but we ask that decisions be linked directly to the real costs to society. We invest vastly more money in Alzheimer's research, for example, which has a much shorter course between diagnosis and death than autism.

Autism is a lifelong disorder which has no apparent inherent impact on longevity. Children diagnosed today with autism will be an economic and emotional burden to the country for the next 70 years.

Nearly 2 years after the passage of the Children's Health Act, its conditions and goals are far from being met. A recent report prepared by the National Institute of Mental Health in February of this year contains what we consider to be several inaccuracies. It reports that $56 million is spent each year on autism, and we believe that these numbers are slightly exaggerated due to accounting numbers of dollars that are spent from related activities. We would like to see those numbers put specifically toward direct research dollars that are focused on autism.

We would also ask our friends at the NIH, when they put out these reports, to show us where the numbers are coming from, so that we continue to maintain a relationship of trust and accountability between the public and the Federal Government. We have been told by the NIH to anticipate the designation of two of the five clinical centers mandated by the act this year. Even this small step took a lot of effort on the advocacy groups' part. The casual attitude of the NIH toward autism does not reflect sufficient urgency in our minds. While it was stated in an NIH report to Congress that there would be an increase to $15 million per year for these centers, it became clear that is not going to be happening in the near-term.

We would like to request that more than two Centers of Excellence be designated in this cycle of funding and three to four more in the next cycle, as the law provides for a minimum of five centers. Time is of the essence. We realize that scientific and medical research moves forward slowly, and I know that from my own experience at the bench. We could double or triple the pace if the NIH were to designate more centers in this cycle now and then an additional number in the next cycle.

I know that there are qualified applicants and centers who are anxious to get started. There have been minor activities by the Federal Government in brain and gene banking, as required by the act, but we expect a larger concerted effort, as described in the legislation.

These brain and gene repositories are vital resources to be able to understand all aspects of the disorder, including the environmental interactions with these factors. The advocacy groups have invested substantial dollars in these resources, and we expect a larger effort from the government.

The NIH also needs to increase its intramural programs in autism. We have been trying, since the beginning at CAN, to develop field-building in which we recruit heavily at major national neuroscience meetings to try to bring people to the field of autism. I know that the NIH recognizes this and is supporting intramural programs, but we believe that it is very important that be one of the goals of the NIH, to develop scientists who are maybe working in labs alongside with the NIH, who are actually working on autism and don't realize that they are because this is a complex disorder that affects many biological systems in the body, including the GI tract and the immune systems.

The Children's Health Act mandated that physician and public education programs be developed to allow for earlier diagnosis and intervention. It is well established that this is currently the most effective means of changing a child's course on the catastrophic course and possibly creating a productive, independent person. The Department of Health and Human Services has failed to move these programs forward.

In New Jersey the advocate groups came together and funded a program called First Signs, which we launched last year at the Autism Caucus. It has been piloted in New Jersey and seems to be successful in training doctors.

It is unacceptable that 49 States do not have a formal mandated training and education program for doctors and the public. People are losing precious time. We lost lots of time with my son because no one knew what he had.

Finally, we have heard that the CDC, also as part of the Children's Health Act, has been prevented from fulfilling its prevalence research studies due to the Family Education Rights and Privacy Act. They have been working with the Department of Education for over a year to allow access to the education records that hold diagnostic information. We think that should be able to be resolved so that the CDC can be allowed to do their job.

The passage of the Children's Health Act was an incredible first step in changing the course of this disease, and the parents want to thank Congress for this. There is great momentum, but it will take much more effort and money than the not-for-profit advocacy groups could ever hope to sustain. We ask Congress to continue to lead us forward and for the NIH and CDC to show leadership in autism.

My son still has autism, of course, and so do hundreds of thousands of other Americans. They need our government agencies to be responsive.

I would like to close by thanking the members of the committee for listening to us and for acting on our requests.

[The prepared statement of Mr. Compton follows:]

Testimony to Hearing on Autism
April 18th, 2002
House Committee on Government Reform

Good afternoon Chairman Burton, Congressman Waxman, and distinguished members of the Committee:

Thank you for giving me the opportunity to testify today regarding the parent/advocate perspective on NIH and CDC research activities on autism.

My name is Doug Compton. I have been an advocate for the autism community for six years, while I was a career scientist studying heart disease. I have recently become the Science Program Director for the Cure Autism Now Foundation. My son Daniel, now nine years old, has autism. There are hundreds of thousands of families like mine throughout our country - families with a child with autism, and our numbers are growing relentlessly, every day. We are part of a massive epidemic of human suffering in the United States as well as the world. We ask that you help us to increase the pace of research funding and activities mandated by the Child Health Act of 2000.

I would like to stress up-front, that you consider my comments in the context of the numbers of people with autism. When Cure Autism Now and other parent advocates came to Congress four years ago, the literature stated an autism prevalence of 4 in 10,000. The advocates stated 1 in 1000. During an advocate/NIH meeting in November 2001, with the CDC present, this number was revised upward to 1 in 250, with extremes as high as 1 in 150 in Brick Township, in my home state. The scientists are debating why these numbers are changing, and the extent to which environmental factors or better diagnosis are playing a role, and we need to find the answer. But what is most important is that everything about this trend represents a crisis --- because it affects children, it's severe, and it lasts a lifetime.

Four years ago my family and I came from New Jersey to the Capitol with others to introduce this important legislation which led to the Child Health Act of 2000. We came with enthusiasm and hope. It was a bright day. I stood proud knowing that our nation's leaders were listening to us. My autistic son stood at a microphone endlessly repeating his favorite script from a video. No one listens to his repetition after a few rounds, except his heartbroken family. And we are the lucky ones. Many people with autism cannot communicate at all.

In October of 2000, we rejoiced at the passage of the Child Health Act. Another milestone, and more hope. We expected rapid implementation of all aspects of the Act. In the years between introduction and passage, the citizens made progress as advocates in the advance of science. States like New Jersey and California passed legislation to fund research. Cure Autism Now's gene bank, the Autism Genetic Resource Exchange, grew to become the world's largest and only open resource for the study of autism genetics. The National Alliance for Autism Research and the Autism Society of America created a brain bank. Together, these and other parent groups funded research to try to identify the causes of autism, from genetics to environmental factors. We have funded brain imaging studies, animal models, and treatment trials. We have closed no doors, as there is still no conclusive evidence as to what causes this thing we call autism. Nor are there universally effective treatments. We continue to push the research agenda. But we need our government to push harder.

While there has been a large increase in funding from the Federal Government, from $5 million to $30 million a year, this is far from sufficient. It is not commensurate with or ambitious enough to address the depth of the human suffering and of the economic hardship which the disorder is placing on affected individuals, their families, and our society. The formula by which specific funding is allocated by the NIH is a mystery to us. Far more money is spent on diseases which effect fewer people. We understand that the NIH has to follow scientific opportunity, but we ask that decisions be linked directly to the real cost to society. We invest vastly more money in Alzheimer's research, which has a shorter course between diagnosis and death, than autism. Autism is a lifelong disorder which has no inherent impact on longevity. Children diagnosed today will be an economic and emotional burden for the next 70 years. We know the course of this disease can be changed through aggressive research.

Nearly two years after passage of the Child Health Act, its conditions and goals are far from being met. A recent report prepared by the National Institutes of Mental Health in February of this year contains many inaccuracies. While it reports that $54 million dollars per year are spent on autism, we believe it is actually spending approximately $30 million. While it reports that the incidence ranges from 1/500 to 1/1000, the data suggests that the rates are as high nationally as 1/250. As this Committee knows, the rates in the Brick Township, NJ CDC study were even higher. We expect such reports from NIH to be accurate, as these inconsistencies do not send the correct message to the public that autism is a crisis and must be treated as a priority.

We have been told by NIH to anticipate the designation of two of the five Clinical Centers mandated by the Act this year. Even this small step took inordinate effort on the advocacy groups' part. The casual attitude of the NIH toward autism does not reflect sufficient urgency. While it was stated in the NIH report to Congress that there would be an increase to $15 million dollars per year, it became clear that the NIH did not plan to increase to this level of funding until 2003. Advocates had to pressure the NIH leaders and hold discussions with the House Oversight Committee just to increase funding from $8 million to $12 million in 2002. We are asking that more than two centers of excellence for autism be designated in this cycle of funding, and three to four more in the next cycle, as the law provides for a minimum of five centers. Time is of the essence. Scientific and medical research moves forward slowly. We can double or triple the pace if the NIH designates more centers now. We know that there are qualified applicants who are anxious to get started. There have been minor activities in brain and gene banking as required by the Act, but the concerted, larger initiative described in the legislation is absent. Brain and gene repositories are vital resources. The advocacy groups have invested substantial dollars to launch these resources, but only a large scale Federal effort will allow them to be expanded and utilized so they can make a difference in this disease.

The NIH also needs to increase its intra-mural programs in autism. Again, insufficient funds are being provided via this well-established mechanism which commonly supports important research in other diseases within the NIH. Autism affects many organ systems besides the brain - the immune and gastrointestinal systems among them - and there are scientists within the NIH whose expertise in other fields could be applied to this disorder with little startup. Yet due to limited support, these scientists are not being brought into the autism fold, making it almost impossible to complete the entire biological picture which is autism.

The Child Health Act mandated physician and public education programs to allow for earlier diagnosis and earlier intervention. It is well established that this is currently the most effective means of changing a child on a catastrophic course into a productive, possibly independent person. The Department of Health and Human Services has failed to move these programs forward. In New Jersey the advocacy groups managed to start an early diagnosis program called First Signs, by spending $200,000 dollars in 1 year, which we launched at last year's Autism Caucus. It is unacceptable that 49 states do not have a formal, mandated training and education program. We must move quickly. The child born today could be spared. In my son' case, we wasted a year of precious time before the word autism was ever mentioned. We lost valuable time for intervention.

Finally, we have heard that the CDC, also a part of the Child Health Act, is prevented from fulfilling its prevalence research due to FERPA issues. They have been working with the Department of Education for over a year to allow access to education records which hold diagnostic information. Why can't such issues be resolved within a year? Again, we feel that the CDC, like the NIH, does not treat autism with the same urgency that it would an epidemic of measles or pertussis.

Passage of the Child Health Act was an incredible first step in changing the course of this disease, and parents thank Congress for this. There is great momentum, but it will take much more effort and money than the not-for-profit advocacy groups could ever hope to sustain. We ask Congress to continue to lead us forward, and for the NIH and CDC to show leadership in autism instead of dragging their heals. My son still has autism, and so do hundreds of thousands of other Americans. They need our government agencies to be responsive, but unfortunately, we have only seen half-hearted, tepid action.

Thank you.

Doug Compton
Science Program Director
Cure Autism Now foundation
(908) 832-2100
dcompton@cureautismnow.org

Mr. BURTON. Members of the committee, we are going to have a vote in about 10 minutes. So what I will do is I will yield to you right now for questions, and then I will stay here. Then I guess, Dr. Weldon, if you can come back and take the Chair, so I can rush over and vote, and then we will keep the hearing going, if that's all right with the vice chair.

So let's start with you, Mrs. Morella. Do you have any questions? I will ask my questions while you guys are running over to vote.

Mrs. MORELLA. I was not the first to arrive here, if you want me to yield to Mr. Horn.

Mr. BURTON. Let's see, I think Dr. Weldon was the first to arrive. So we will start with Dr. Weldon then. Then we will go to you, Mr. Horn. Is that all right?

Dr. WELDON. Thank you, Mr. Chairman.

Mr. Grossman, the agenda that you put together, could you just tell me a little bit about how you came to those recommendations? You had some figures in there. Did you have a committee that helped you work on that?

Mr. GROSSMAN. These figures were actually put together inhouse at ASA. We have been inundated recently by numerous media in the United States, as well as in Europe, to support the data about explosion in the prevalence of autism. We were challenged to find any good studies or any information out there. We reviewed extensively all the literature that we had available. We put it out to many people that are on our panel of professional advisors, other consultants that we know, professionals in the field, to provide us with information that would support the data, show some meaning to the statistics that we feel we need to support showing this increase.

Frankly, there is nothing out there. There are no good studies. This is all anecdotal evidence. So basing what we know on the ranges that exist that are commonly being bantered about and accepted, we put together a formula of approximately what it would take to fund at this point the research.

If you are specifically addressing the research and like the $500 million, for example, we are looking at the cost of autism, which is, we conservatively say, $20 billion annually. That is based on what we figure is the prevailing—the numbers, conservative numbers, of a half million times about $40,000 per person for treatments per year, which is actually a low figure.

Dr. WELDON. Did you have any professionals help you put this together? Tell me a little bit about ASA. How many members do you have and how many staff?

Mr. GROSSMAN. There's 200 chapters throughout the United States. We have approximately 25,000 members throughout the United States. We have a panel of professional advisors made up of about 20 experts in the field. Our membership extends beyond the 24,000. We don't exclude anybody that has an interest in it. Our office here is located in Bethesda, MD. We have a staff of, I believe, seven people.

The committee was made up of staff and people on our board, as well as professionals that we were consulting with. We would gather the information, extend it out through conversations, and then come back to put that information together.

The $500 million, it is, to be frank with you, a drop in the bucket compared to really what needs to be done to address this. It is what we felt was a conservative number to approach the government with.

We feel also that much has to be done. That is why there is a 3-year ramping up of those figures, because the infrastructure of what is available today in America to support autism research is not there. It needs to be developed to get us to that point.

Dr. WELDON. I am glad you raised that point because this is one of the issues I have gotten into with the NIH. I was very pleased that Mr.—is it "Mr." or "Dr." Compton—Mr. Compton, he alluded to this issue, that if we were somehow able to get an appropriation through this year for $500 million, the NIH would be really hard-pressed to find a way to spend that much money. There are not a lot of people prepared to do the research studies.

I don't recall, did you say anything in your recommendations about behavioral treatment at all? I know we need to do a lot of basic science treatments in terms of the pathophysiology and preventions, but dealing with all of these older kids and adults, it seems to me there is really not a good body of knowledge. Some of it seems to be emerging.

Mr. GROSSMAN. Yes, I mentioned in my testimony that virtually it is nonexistent today, the research that is going on on the therapeutic aspect or the treatment aspect of autism, and we specifically ask for a ramping-up over the next 5 years to a level of about $100 million, based specifically on the behavioral treatment, therapeutic, clinical aspects of autism.

Dr. WELDON. I am running out of time. I have one more question. Your health insurance policies cover virtually nothing, correct? You get a diagnosis of autism. Your typical Blue Cross/Blue Shield, whatever, they will not cover any types of therapies, treatments whatsoever, correct? So these families are literally on their own? It is all out of pocket?

Mr. GROSSMAN. Yes, essentially, it is all out of pocket. The only avenue that is available to us is services provided to us by the educational system.

It is funny that you brought this up because that is an important issue that we are grappling with on the insurance that would require a full hearing on its own. Recently, California was able to pass legislation mandating that developmental disabilities, and specifically autism, be covered under the medical insurance plans in that State.

Dr. WELDON. Thank you, Mr. Chairman.

Mr. BURTON. Mr. Horn.

Mr. HORN. Thank you, Mr. Chairman.

I have been very interested in what you had to say, and there is a few simple things I need to know. Is it Asperger's? What is this disease?

Mr. SHORE. Asperger's syndrome.

Mr. HORN. Asperger's. Could you tell me the difference between autism and that? I see in our lists here that, after Mr. Shore's bit, that he is a doctoral candidate at Boston and also has Asperger's disease, sometimes known as high-functioning autism. I would like to just get a feel for what is that particular part of this.

Mr. SHORE. Well, the major difference between autism and Asperger's syndrome, we talked about the autism spectrum, ranging from severe to light. At the severe end that is what we consider the classical canner's autism. That is what most of society thinks of children with autism. These are the children that we see being nonverbal, having tantrums whenever there is a change in the environment, perhaps being self-abusive, a strong, you might say, or severe lack of body-to-environmental awareness.

As we move to, say, the moderate part of the spectrum, we have more environmental awareness. These children have more receptive language abilities. So they understand more than they can speak. They may be considered being limited verbal, perhaps having one or two-word phrases and not very many of them.

At the high-functioning end, and Asperger portion of the spectrum, that is the lightest end of the spectrum, and we actually see more people over there than at the severe end. These children, particularly with Asperger's syndrome, according to the DSM–4 revised, they don't have any delay in communication, but the issues of socialization—I should say verbal ability. There are still difficulties in communication. So we see major issues in communication, socialization, restricted interests, and repetitive motions.

Now when we move to Asperger's syndrome, these are the children that strictly, according to the DSM–4, have never lost their verbal ability. Applied a little bit more loosely, these are children, to need to be specific, who had have verbal ability until 18 months, the bomb hits; we lost verbal ability and we get it back. So usually by around the age of 4 or 5 or so, maybe 6, the verbal ability is back. It is pretty much at the level of most other people, but the language is used, you might say, in a unique way and there is often difficulties with dealing with abstract subjects, you might say reading between the lines, which translates to difficulties in being able to determine what other people's intents are, if it is not spoken in a very concrete, clear way.

The important thing to keep in mind, though, is that with both autism and Asperger's syndrome the issues are coming from the same place. You are still dealing with the communication issues in one way or another. The most severe end, lack of verbal ability; the lighter end, Asperger end, verbal ability, but difficulties in dealing with pragmatics or what is between the words, you might say.

You still have restricted interests, special interests they are called, as Tony Oustwich talks about them, interests that are so strong that they actually interfere with daily functioning. What the current educational—what people are beginning to learn in education is to use these special interests in order to facilitate learning.

Repetitive motions, that is often the self-stimulatory behavior that we see, and an issue that the DSM–4 doesn't cover that I find present throughout the autism spectrum, sensory integration issues. In that case what we are talking about is some of the senses are turned up too high, way too high. I know people on the spectrum that if they were in a room like this, I would see their eyes vibrating like this, and they would say, “We've got to get out of here.” Because they actually see the cycling of the fluorescent lights above that screen there. Some senses are up too high, some are too low, and other senses, information that comes in from the senses is distorted or unable to use the information, you might say, in a typical manner that other people would.

Mr. HORN. Mr. Compton, is there anything you want to add to this definition?

Mr. COMPTON. No, I think that Stephen described it fairly well.

Mr. HORN. So I would be curious about what type of either biochemical, chemical, or whatever, to work on some of these things. Would you work with autism as well as Asperger's approach or are there certain other ways that would call for a different type of scientific approach?

Mr. COMPTON. Well, I would like to address one of the aspects that Stephen brought up, which would be that, obviously, people with Asperger's who have more communication are more readily, I believe, have their symptoms remediated by behavioral teaching and interventions.

In the area of I think what you are referring to as pharmacotherapy, I would say that we are in the infancy of that. I just returned from an autism clinical trial task force that our foundation held in Los Angeles last week, and I believe to this day there have only been seven well-controlled, double-blind, placebo-control clinical trials in autism. Because we don't know what the underlying neuroanatomical substrates are that are aberrant or the biochemical pathways that are aberrant across the spectrum, it is very difficult at this point to design targeted therapeutics for the disease.

We are still not certain how many disorders are represented under the umbrella of the autism spectrum. I would be certain from the data that I heard last week that certain treatments will actually give serious adverse effects to some patients, increase their hyperactivity and motor stereotypies, cause restlessness, decreased sleep, whereas in another subset of patients we may see improvements with these types of therapies. So I would say that it is too early in the field to generalize about any of this.

When we think about treatments that go beyond the brain to the GI tract or to immune dysfunction, they we have opened up an even wider area that we need to study. All of this reflects back on the fact that we need to cast a wide net and we need more money, and we need more intramural programs, because despite the fact that we have made tremendous progress in the past 5 years through a lot of the advocacy groups funding research and the NIH's efforts with the CPEA programs and the newly funded research, we are far from having any clue as to how to develop effective therapies.

Mr. HORN. Do you feel like the report to Congress is an accurate representation of what is happening in autism research?

Mr. COMPTON. Well, I would say, I was talking with Dr. Foote before this, and we don't have a line-by-line itemization of each dollar that is spent, but when we look at the directed programs, which we are very happy that money is being spent there, we don't see it add up to $56 million. Now that can be due to something that as a scientist I firmly agree that we need to field-build and we need to fund research in other areas, but in the autism community I believe that we need to focus on autism. When there are basic research questions being addressed which could include development of brain imaging techniques or genetic techniques, or what have you, for those to be lumped under the category of spending on autism, if in fact that is being done, I'm not certain if that is being done, but we do see an inconsistency that could be explained by this phenomenon. That is acceptable in the sense that the intramural researcher, if it is being claimed as being money spent on autism, that the intramural researcher is actually doing autism research or at least collaborating with a researcher who is doing autism.

I would suggest, if possible, that there be a detailed report from the Public Information Officers, so that we would feel as a community that there was an open dialog on this issue.

Mr. BURTON. Mr. Horn, can we go to Mrs. Morella, and we'll come back to you in just a moment? We are going to have a vote here, and I want to make sure she has an opportunity.

Mr. HORN. I have got to dump some stuff off for later things, so I will try to come back.

Mr. BURTON. That would be fine.

Mr. HORN. OK.

Mr. BURTON. Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman.

I think as people who are here assembled probably know, you have had a real commitment to try to unlock those secrets of autism. Had I thought about it earlier today, I would have worn my autism ribbon, which is puzzle pieces, you know, seeking to come together, but they have yet to do that. But we on this committee have been seeking the data, wanting to know more about what studies are being conducted, and are rather frustrated about the fact that so much needs to be done and has not been done yet. That is the purpose of the meeting. So I thank you for this hearing, Mr. Chairman, and for your commitment.

Mr. Grossman, you probably know that I represent Bethesda, MD, where ASA is located, very proud of the fact that is your national headquarters.

Mr. Shore, I am a graduate, as is my husband and a couple of my kids, of Boston University. I congratulate you on pursuing doctoral studies, and I thank Mr. Compton and Ms. Lerner for being here.

Also, I represent the National Institutes of Health, and I am very proud of the work that they do, and I am very proud of the fact that in the budget that we approved on the House side, and the President submitted, there is like a 16 percent increase for NIH, which is going to bring it to that 5-year plan of having doubled the budget of NIH during that 5 years, by 2003.

Now the question I want to ask all of you, or however time will allow, is: NIH is going to be at the table right after you. If you had a chance to ask them a question or if you had a chance to say to them, "How do we work together"—I mean, are they providing information? Is there a partnership? Does there need to be more of a partnership? I know their intent is very good. So it could be that you want to say something for the record and that you would like to ask them something or make a suggestion.

I would like to start off with you, Mr. Grossman.

[The prepared statement of Hon. Constance A. Morella follows:]

Government Reform and Oversight
Response Adequate?
(NIH and CCD Funding)
April 18, 2002/Rm. 2154

Constance A Morella

Mr. Chairman, I appreciate your efforts to hold this hearing on autism. I look forward to hearing the testimony of the witnesses.

I would like to extend a warm welcome, we do afterall have warm weather, to the witnesses. Several who have connections with Montgomery County, which I am honored to represnet.

o have traveled far to tell us their personal story, first hand.

***Mr. Lee Grossman*, who has traveled from Honolulu, Hawaii, to share with us his personal story first hand.**

Mr. Grossman is President of the Autism Society of American which is located in Bethesda, in my district. (Mr. Grossman is an autism parent).

I also welcome from the National Institutes of Health:

Mr. Steven Foote,
(National Institute of Mental Health)

and Ms. Ann Willoughby,
(National Institute of Child Health and Human Development).

I am pleased to have representatives from NIH here today and I look forward to their testimony.

The doubling of NIH's budget, and its funding for

biomedical research has been, and will continue to be one of my most important priorities.

As some of you may know, the National Institutes of Health is in my district.

I have been a leading proponent of increased funding for NIH. I am firmly committed to the goal of doubling the NIH budget by FY 2003.

This commitment began in 1998, when Congress successfully enacted a 15% increase in the NIH appropriation for FY 1999.

I am pleased to tell you that FY 2002 appropriations contains $23.6 billion for NIH. This is nearly $3 billion more than FY 2001.

I am very pleased that President Bush has in his budget plan has proposed spending a record $27.3 billion for NIH in 2003, enough to complete a five year doubling of NIH'S budget.

This proposal amounts to an increase of $3.7 billion or almost 16 percent, over the current year's $23.6 billion.

This will be the largest dollar increase in NIH'S history.

We need to use this funding wisely, which is why I welcome today hearing on NIH and CCD funding of autism.

I have no doubts that we do need to increase funding

for autism research.

As many of you know, under the Chairman's leadership during the past several years this Committee has held numerous hearings on autism. We on the Committee are frustrated with the lack of data on autism, and the lack scientific studies.

We have begun the task of getting data, and conducting studies, and it goes without saying that it cannot be done soon enough for those with autism and their families.

Autism has stolen many of our children who were once happy with bright smiles, and has left us with children that we struggle to communicate with, we struggle to educate, and we never stop worrying about how to give

them some semblance of a secure and loving future.

I come today to learn more about what we are doing in research of autism, its relationship, if any with vaccines and/or environmental effects. I hope that learn today on what is the appropriate nest steps for this Committee, and for the federal government to take.

Thank you.

Mr. GROSSMAN. The relationship that ASA has developed with NIH over the last year has been very, very positive. The communication has been——

Mrs. MORELLA. I would add CDC, too.

Mr. GROSSMAN. Right, and the CDC has been very, very positive. There's been much communication between us in terms of us addressing our concerns with them, and them providing us answers to those issues.

I am the representative on the Interagency Autism Coordinating Committee also, which is a forum which started, our first meeting was in November, which summarizes at that first meeting all the activities of the Federal agencies and will be an organization or committee going forward that, hopefully, will be coming forward with more suggestions.

In looking at the report to Congress, for example, which describes in detail what NIH and CDC is doing, it is pretty much I believe they have been mandated at this point to do. What we would need to do, and I don't have any specific suggestions for them at this point, is that we need collectively, the autism community, as well as the legislative branch and the administration, needs to provide them with the resources that they need specified for autism to expand their research efforts, to expand the service delivery.

This incorporates a much broader base than just those two agencies, NIH and CDC. This is a national emergency. It has reached epidemic proportions. It is not only a two-Federal agency issue. It is a national issue, and we need to bring it forward as such.

Mrs. MORELLA. Would any of the other panelists like to respond to that? Yes, Mr. Compton?

Mr. COMPTON. Yes, I would like to respond. Despite the fact that I may have sounded critical about the NIH, I am absolutely thrilled with what has been going on since my son was diagnosed. When I first went to my first meeting and I saw Dr. Bristol Powers speak, I was very impressed, and I still maintain tremendous hope.

I think that the NIH and its subdivisions, the NIMH and NICHD, etc., and the CDC need more money. It may sound ridiculous, but $56 million is not very much money when you look at the vast number of systems that are affected in autistic individuals.

Beyond the medical research, at a biological level, there is a need, for instance, to develop protocols, to measure outcomes in clinical trials, and it does not just mean clinical trials of pharmaceuticals or interventions. It means clinical trials of educational interventions, which need to be held to the same degree of scrutiny. A lot of families are wasting money on therapies that are not biologically based, which are probably also not helping their children.

I would like the NIH to break down any of the barriers among the agencies and try to promote as much collaboration as possible. When it comes down to it, I think it is all about money and the prioritization and, as we talked about earlier, the way that decisions are made to weigh the cost of the disease to society versus the cost of investment. I think that needs to be looked at critically, and to develop the intramural programs such that there is true focus of related fields to this disease. It not only gets you more bang for your buck, but creates the cross-talk and the collaborative environment that I think is going to be necessary to correct the situation.

Mr. SHORE. I have something to add. I think it is a great start. We need more. We need more work on collaborating, and I see a lot of in-fighting between the autistic community. If we just look at educational interventions, like some of the ones that I have named, there is no—I haven't found any study where anyone who has taken a serious look at comparative methodology. What I find in looking at the different methodologies such as the ones I have listed, a lot of them are doing similar things, but they are calling them different names.

Also, because of such wide differences in people with autism, it is a wide spectrum. There are some children where a particular method works much better than another method. I would like more research. Actually, that is going to be part of my doctoral dissertation, but that is just a start. I am just going to validate the instrument.

What I am talking about is something that will be able to allow us to match the child to the method, because at this time it is a bit like the Keystone Cops: "Oh, this method is the greatest; that's all there is. The other methods aren't worth even thinking about." We should be kind of ashamed of that. We should all be working together and corroborating.

Mr. Compton's suggestion of outcome studies, they are very, very important, longitudinal studies, hard to do, but we need them.

Mrs. MORELLA. Thank you. You have all been very helpful in responding to that question. Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Mrs. Morella.

One of the things that has concerned me has been the large incidence of autism being created, I believe, by things like thimerosal, which includes mercury in that preservative. In Russia, in the 1980's, they recognized problems. As a matter of fact, we just got a letter that we received this week from a professor of medicine at the Academy of Medical-Social Management in Russia, and this letter details the history of concern about thimerosal in vaccines and injury. This is a concern, as I said, that reaches back to the eighties.

I would like to specifically note that Dr. Krashenyuk states, "starting vaccination against hepatitis B of premature infants at age 2 months . . . when they reach a weight of 4 kilograms is recommended in the U.S. From our point of view, this practice is undoubtedly harmful, since it does not take elementary notions of the infant's immunity into account—up to 1.5 years of age the infant does not have its own immune protection, and is protected only by the mother's passive immunity." And then he goes on to say, "It is impossible today to deny the fact that this preservative," thimerosal, "can cause severe post-vaccination complications in children."

[The information referred to follows:]

A. I. KRASHENYUK, Doctor of Medicine, Professor, Head of the Hirudotherapy and
Natural Methods of Treatment Chair of the Academy of Medical-Social
Management
(Saint Petersburg)

THIMEROSAL (MERTHIOLATE) AND THE PROBLEM OF PRESERVATIVE IN VACCINES

Thimerosal (merthiolate) is an organic compound of mercury, used in a concentration of 1:1,000 as a disinfecting agent, for the processing of skin and mucous membranes among other purposes. Its LD_{50} in mice is 66 mg/mL for subcutaneous administration and 45 mg/mL for intravenous administration.

Thimerosal is added as a preservative to many inactivated vaccines. Before use in the production of vaccines, thimerosal is monitored for the absence of free mercury. In the majority of vaccines used in Russia, thimerosal is present in a concentration of 1:1,000 (DPT [AKDS], DT [DT], and DT-R [diphtheria toxoid-reduced/tetanus or ADS-M], some anti-influenza and anti-meningococcal vaccines); in hepatitis B vaccines, in a concentration of 1:20,000. Thus, 0.025 mg of thimerosal is contained in a single dose of anti-hepatitis vaccine (0.5 mL).

The addition of a mercury-containing preparation to mass consumption vaccines has long since aroused anxiety. In particular, the virologist, G. P. Chernovskaya, who **correlated 2,500 cases of severe post-vaccination complications in children**, made relevant presentations to various levels of authority in the 1980s. However, technological resources did not permit the total avoidance of thimerosal in vaccines at that time, all the more so since its replacement by other preservatives offered dubious advantages. The WHO [World Health Organization] also shared that point of view at that time.

In the view of a number of authors, thimerosal may sensitize children with atopy in rare instances [1]; however, in each individual case, the role of this preparation in particular is difficult to prove, since it is administered with other possible allergens.

At the present time, debate on the possible adverse effect of thimerosal in vaccines has started up again; the potential danger of increasing its dose through the simultaneous use of several vaccines containing this preservative has been underscored.

Taking the large dose of thimerosal per 1 kg of body weight into account, opinions have been advanced regarding its potential danger for newborns, and especially for premature children.

In this connection, starting vaccination against hepatitis B of premature infants at age 2 months (provided there is a negative finding when testing is done for HbsAg in the mother), i.e., when they reach a weight of 4 kilograms, is recommended in the U.S. [2].

From our point of view, this practice is undoubtedly harmful, since it does not take elementary notions of the infant's immunity into account - up to 1.5 years of age, the infant does not have its own immune protection, and is protected only by the mother's passive immunity.

Lobbying of the interests of companies manufacturing the vaccines in question is clearly discernible here.

Of course, the total avoidance of thimerosal in vaccines would be extremely desirable, and a number of manufacturing companies are working on this. There already are vaccines against Haemophilus b and acellular anti-pertussis vaccines with a reduced amount of thimerosal; vaccines against hepatitis B that do not contain thimerosal have also been created.

The use of vaccines without thimerosal in Russia would be of great significance, since it is impossible today to deny the fact that this preservative can cause severe post-vaccination complications in children.

Literature:

1. Patrizi, A., Rizzolli, L., et al. Sensitization to timerosal [*sic*] in atopic children. Contact Dermatitis, 1999; 40(2): 974-979 [*sic* - Rizzolli = Rizzoli, and page range 94-7, according to Medline]
2. Pickering, L. K. (ed.) Red Book. Report of the Committee on Infectious Diseases. Elk Grove Village. Ill. American Academy of Pediatrics. 2000

Mr. BURTON. That same conclusion has been reached in countries like Norway, Sweden, and Denmark has not allowed any thimerosal in any of their vaccinations since 1990.

Was there any connection when your children became vaccinated and the onset of the autism? Did you notice it in close proximity? Any of you at the table?

Ms. LERNER. Not me personally, but I can tell you that, because of the controversies surrounding the MMR, I was very concerned when my son had to get his second round of vaccinations. So in New York State they allow you to get a titers test to determine what the immunization level is for the child and whether or not it necessitates a second vaccination. As a result of that blood test, it showed my son still had very high levels of the immunity in his system, which led me to believe that, for whatever reason, based on his neurology, he was not able to properly metabolize the original vaccination that he got. Now Ben's symptoms date back to, I think, infancy, but there is demonstration that obviously, based on their compromised neurology, that they can't process these vaccinations in the same way.

Mr. BURTON. In the audience, how many have noticed a change in your child after the vaccinations?

[Significant show of hands.]

Mr. BURTON. OK, I just wanted to know that from the audience.

Mr. GROSSMAN. Mr. Chairman, if I can comment on that?

Mr. BURTON. Yes, sure.

Mr. GROSSMAN. Personally, I didn't recognize any change in my son. We knew something was wrong, and it was about at the time that he would have received his vaccination, but it took us a while before we figured things out. It actually was my sister, who is a practicing psychologist in Philadelphia, that took a trip with him to the mainland, and she noticed that I had to get some interventions for him, something was terribly wrong, and she threatened to take my son away from me unless I did.

But I think the stories that I have heard that many of our members tell, that many of these people in the audience will tell you, is that they believe that there is evidence that there is a direct linkage, a direct causation of vaccines causing their child's autism. I think it is imperative for us, the advocates in the room, for ASA, and for Congress, for the lay public, to stand together to get this question answered, answered immediately.

We are perhaps creating generations of children that are severely getting injured through vaccinations. We don't know that, but there is a growing body of evidence such as what you are reporting from Europe that really draws into question what is going on. So whatever is necessary from you to give us direction on what we need to do, we will support that.

Mr. BURTON. How many members? You said you had 25,000 members in your organization?

Mr. GROSSMAN. 25,000 members, and we have an extended membership of people that are signed up as advocates that actually don't pay a membership. Our reach, we believe, extends into certainly 50,000 to 60,000 people at any one time.

Mr. BURTON. Now the organization that you are connected with, Ms. Lerner, how many members do you have? Do you know?

Ms. LERNER. It is hard to actually quantify that because we are an umbrella organization, and organizations like ASA, CAN, NAR, they are all part of our group. So we would be collectively whatever their membership——

Mr. BURTON. So it would be kind of included in the same?

Ms. LERNER. Yes.

Mr. BURTON. How about you, Mr. Shore?

Mr. SHORE. Yes, the Asperger's Syndrome Coalition of the United States, I believe we have a reach of probably 2,000 to 3,000 by the time the mailing that is rebound all over the place.

Mr. BURTON. OK, and your organization?

Mr. COMPTON. CAN's membership, I am not sure if the membership is completely autistic, for autistic families, runs at about 35,000.

Mr. BURTON. Around 35,000? Well, somewhere between 60,000 and 100,000 people can be reached by your organizations, and I am sure there are other organizations here that I am familiar with. I would like to just restate one more time what I said earlier. That is that the squeaky wheel gets the oil in this town.

I cited the amount of money that is being spent for the various research projects including AIDS and diabetes, and so forth, and the comparison of that with the money that is being used for autism research. We are going to be funding at a much higher level research at NIH in the coming years, and this is the time for you to be proactive.

I cannot stress enough how important it is, and I will be doing my part here as well, and other Members will, to contact your Congressman, your Senators. Don't just write to one; write to them all, if you can, in your State, and make sure and tell your members, make sure to tell them how important it is that there be an increase and an adequate amount of funding and the proper research into rehabilitation for children and prevention, to make sure that we find out what is causing this, not just possibly things like mercury in vaccines, but other things, maybe other toxic substances that may be in the vaccines, maybe mixing too many at one time. The immune system might not be able to handle that much. Maybe it is the MMR vaccine. I don't know what all the circumstances are, but that research needs to be done, and it is going to cost money. It is going to take pressure to be exerted from folks like you folks.

Yes, go ahead.

Mr. WAXMAN. I want to join you in supporting more research because there is still so much we don't know about autism. We do not know how prevalent it is. We need to do the research in order to understand what the actual prevalence of autism is and whether the increases in cases is due to better diagnosis or to environmental causes that can be prevented, or some combination of factors.

We also don't understand the causes of autism, nor do we have a cure. That is why Congress enacted the Children's Health Act of 2000. This act, which I strongly supported, increased funding for autism research. But we need to do more than wait for the research. The National Academy of Sciences has made it very clear in a report last year that early intervention is critical for educating and treating autistic children. It is incumbent on the medical and educational communities to identify children in need of services as early as possible, and it must be a high priority for Congress to assure that all children with developmental delays, including autism, have access to scientifically proven treatment and educational services that can maximize their potential.

I appreciate the contribution of all the witnesses who have testified at these hearings and educated us about what it is like to live with a child with autism or to live with autism themselves. I want you to know that the experiences you have recounted are part of the record. They will be shared with our colleagues, and they are going to have a genuine impact.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Henry A. Waxman follows:]

For the record

Statement of the Honorable Henry A. Waxman
Ranking Minority Member
Committee On Government Reform
Hearing on "The Autism Epidemic- Is the NIH and CDC Response Adequate?"

April 18, 2002

I am pleased today that we are having our yearly update on progress in research to understand autism. Chairman Burton deserves credit for increasing awareness about autism through these hearings.

There is still so much we do not know about autism.

We do not know how prevalent it is. Some clinicians and parents have testified in previous hearings that they are seeing an increase in the number of autism cases. We need to do the research in order to understand what the actual prevalence of autism is and whether the increase in cases is due to better diagnosis, or to environmental causes that can be prevented, or to some combination of factors.

We also do not understand the causes of autism, nor do we have a cure.

Because there is so much we do not know, Congress enacted the Child Health Act in 2000. This Act, which I strongly supported, increased funding for autism research. I look forward to hearing from both our government and our private witnesses how this law has advanced research.

But we must do more than wait for the research. The National Academy of Sciences made it very clear in a report last year that early intervention is critical for educating and treating autistic children. It is incumbent on the medical and educational communities to identify children in need of services as early as possible. And it must be a high priority for Congress to assure that all children with developmental delays, including autism, have access to scientifically proven treatment and educational services that can maximize their potential.

One area where we have made progress is in understanding whether parents need to fear that vaccines are causing autism. Last year we heard from the Institute of Medicine about their review of the theory that the measles mumps and rubella vaccine may cause autism. The IOM concluded that this theory is not supported by the scientific and medical evidence.

In a separate report, the IOM reviewed the theory that the mercury-containing preservative, thimerosal, contributes to developmental delay. The IOM concluded that this theory, while biologically plausible, is unproven.

While these findings are encouraging, more research is clearly warranted. I am pleased that CDC and NIH have embarked on a series of well designed studies to address unanswered questions. It is also encouraging that vaccine manufacturers have stopped using thimerosal in vaccines.

I appreciate the contribution of all the witnesses who have testified at these hearings and educated us about what it is like to live with a child with autism or to live with autism themselves. I want you to know that the experiences you recount are having a genuine impact.

I thank the witnesses for appearing today and I look forward to their testimony.

Mr. BURTON. Thank you, Mr. Waxman. We do appreciate what you have done in the past to help in this area.

Let me just say to this panel that we really appreciate your testimony. We hope you stick around to hear what the NIH people have to say and the people from our health agencies.

We are going to take a brief recess here. Dr. Weldon will start the hearing, and I will be back as soon as I get a chance to vote on the floor.

We stand in recess at the fall of the gavel.

[Recess.]

Dr. WELDON [assuming Chair]. Chairman Burton asked me to reconvene the hearing.

So I would like to again convey his thanks to the first panel, and I would like to ask our next panel to come forward and take their seats.

The committee will now resume. On the second panel we have Dr. Steven Foote, Director, Division of Neuroscience and Basic Behavioral Science, National Institute of Mental Health, at the National Institute of Health, and Dr. Coleen Boyle, Associate Director of Science and Public Health, National Center on Birth Defects and Developmental Disabilities. And we have a third panelist, is that right? You are going to accompany Dr. Boyle, OK. And your name is?

Ms. WHARTON. Melinda Wharton.

Dr. WELDON. OK, could you all please rise?

[Witnesses sworn.]

Dr. WELDON. Let the record indicate that the witnesses indicated in the affirmative.

I want to thank the panelists for being here. I would ask you to try your best to summarize your comments to approximately 5 minutes, and we will begin with you, Dr. Boyle. Please proceed.

STATEMENTS OF COLEEN BOYLE, ASSOCIATE DIRECTOR FOR SCIENCE AND PUBLIC HEALTH, NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY MELINDA WHARTON, DIRECTOR, EPIDEMIOLOGY AND SURVEILLANCE DIVISION, NATIONAL IMMUNIZATION PROGRAM, CENTERS FOR DISEASE CONTROL AND PREVENTION; STEPHEN FOOTE, DIRECTOR, DIVISION OF NEUROSCIENCE AND BASIC BEHAVIORAL SCIENCE, NATIONAL INSTITUTE OF MENTAL HEALTH, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND ANN WILLOUGHBY, DIRECTOR, CENTER FOR RESEARCH FOR MOTHERS AND CHILDREN, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Dr. BOYLE. Good afternoon, Congressman Weldon and members of the committee. I am Dr. Coleen Boyle, Associate Director for Science at the National Center on Birth Defects and Developmental Disabilities at the CDC, and I am accompanied by Dr. Melinda Wharton, who is the Director of the Epidemiology and Surveillance Division at the National Immunization Program at CDC.

First, I would like to thank you for the opportunity to update you today on CDC's activities related to autism that have occurred during the year since your last hearing. I would also like to thank the parents, the autism advocacy groups, and Mr. Shore for sharing their concerns with us about autism.

The committee requested that CDC testify about the problems of autism and what we know about the apparent increase in rates. We were also asked to discuss the timeline for implementation of the research recommendations from the IOM evaluation of the autism vaccine-related issues as well as CDC's funding for autism research. We are prepared to discuss these issues.

The committee also requested that we address research efforts conducted by the CDC into treatments for autism spectrum disorder. CDC has not conducted research into the treatment of autism spectrum disorders since the NIH is the agency responsible for such clinical research.

Last year I told you about the report of a prevalence study that has already been mentioned today in Brick Township, NJ. That investigation found rates of 6.7 and 4.0 per thousand children for autism spectrum disorder and for autistic disorder, respectively.

This year we can report on the prevalence of autism spectrum disorder in the metropolitan Atlanta Disabilities Program. This report shows a prevalence of autism spectrum disorder of 3.4 per thousand children, as you have already heard. We believe this to be a minimum prevalence and that most of the cases that we have included are actually autistic disorder. In general, the Atlanta rate is similar to that which we found in Brick Township. We cannot determine whether the rates are increasing or not because we don't have comparable data from earlier years, but we will continue to monitor the current rate closely.

We can also not yet generalize for a prevalence for the U.S. population. The population in Brick Township was very small, about 9,000 children, and the population monitored in metropolitan Atlanta is much larger, close to 300,000 children, but we cannot assume that is representative of the U.S. population. Determining if there are regional differences in autism prevalence really requires data from other regions of the country.

To address this need, we have implemented a State autism monitoring program. In fiscal year 2000 we funded five States to track autism. In fiscal year 2001 we funded four Centers on Autism and Developmental Disabilities Research and Epidemiology for the purpose of not only collecting prevalence data, but for conducting collaborative epidemiologic studies to try to begin to identify causes and preventable risk factors for autism.

With these programs, plus the one that CDC runs in Atlanta, we have now nine States involved in monitoring the prevalence of autism. With the new funding that we have received in fiscal year 2002, we expect to add at least three programs, bringing the total up to 12 States that will be tracking autism prevalence.

Monitoring the prevalence of developmental disabilities such as autism provides a number of challenges, including identifying proper sources for case information. Unlike birth defects that are more easily identified in the first year of life, developmental disabilities are diagnosed later in childhood and may require nontraditional sources for public health monitoring.

Collecting data from these sources has proved challenging. CDC will continue to work with colleagues in other agencies to try to address this important issue.

In 2000, CDC and NIH contracted with the Institute of Medicine to establish an independent expert committee to review the hypotheses about existing and emerging immunization safety concerns. Some researchers have suggested that the receipt of either the MMR vaccine or thimerosal-containing vaccines has been associated with various neurodevelopmental disabilities, including autism.

The IOM was asked to review the available information on these issues. In the March 2001 IOM report regarding the association between MMR vaccine and autism spectrum disorder, the committee concluded that the evidence favors rejection of a causal relationship at the population level between the MMR vaccine and ASD.

In October 2001 the IOM Immunization Safety Committee published a report on the possible association between thimerosal-containing vaccines and neurodevelopmental disorders. In this report the IOM concluded that the evidence is inadequate to accept or reject a causal relationship between exposure to thimerosal vaccines and the neurodevelopmental disorders of autism, ADHD, and speech and language delay.

In these reports IOM also made specific recommendations for a number of epidemiologic studies. The CDC has initiated a broad range of studies to better assess these findings as well as to address recommendations by the IOM Immunization Safety Review Committee. These studies are discussed and detailed in my written summary.

CDC remains committed to collecting accurate data on the prevalence of autism and to conducting studies to find its causes. We want every child to be born healthy and to grow and develop normally, so that they are able to lead productive lives. We are dedicated to continuing our work to identify what causes autism and how it can be prevented.

We appreciate your attention to this problem and we look forward to working with you, Dr. Weldon, and other members of the committee.

[The prepared statement of Dr. Boyle follows:]

Testimony
Before the Committee on Government Reform
United States House of Representatives

CDC Activities Related to Autism

Statement of

Coleen Boyle, Ph.D.

Associate Director for Science and Public Health,
National Center on Birth defects and Developmental Disabilities,
Centers for Disease Control and Prevention,
U.S. Department of Health and Human Services

CDC
SAFER • HEALTHIER • PEOPLE

For Release on Delivery
Expected at 1:00pm
on Thursday, April 18, 2002

Good afternoon Mr. Chairman, Congressman Waxman, and members of the Committee.

I am Dr. Coleen Boyle, Associate Director for Science and Public Health in the National Center on Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention (CDC). I am accompanied by Dr. Melinda Wharton, Director of Epidemiology and Surveillance Division, National Immunization Program, CDC. Thank you for the opportunity to update you today on CDC activities related to autism occurring during the year since your last hearing.

CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. The Committee requested that CDC testify about prevalence of autism and what we know about the apparent increase in rates. We were also asked to discuss the timeline for implementation of the research recommendations from the Institute of Medicine's evaluation of autism-vaccine related issues and CDC's funding for autism research from FY 1999 to FY 2004. We are prepared to discuss these issues.

The Committee also requested that we address research efforts conducted by CDC into treatments for autism spectrum disorder. CDC has not conducted research into treatment of autism spectrum disorders since National Institutes of Health (NIH) is the agency with responsibility for clinical research.

CDC's Efforts to Track and Evaluate Increased Rates of Autism

Autism spectrum disorders are a group of life-long developmental disabilities caused by an abnormality of the brain. Autism spectrum disorders are characterized by problems with social interaction and communication skills, and by the need for sameness or repetition in behavior. ASD includes autistic disorder, pervasive developmental disorder - not otherwise specified (including atypical autism), and Asperger's disorder.

Since last year's congressional hearing on autism CDC has increased our activities that will contribute to our understanding on the actual prevalence of autism and autism spectrum disorders. Last year I told you about a report of a prevalence study of autism in Brick Township, New Jersey, where there was concern by the local citizens that the number of children with autism in the community seemed unusually high. The investigation found rates of 6.7 and 4.0 per 1,000 children for autism spectrum disorders and autism, respectively. The previously accepted background rate of autism had been about 1-2 per 1,000 children.

This year we can report on the prevalence for autism spectrum disorder in Metropolitan Atlanta from CDC's Metropolitan Atlanta Developmental Disability Surveillance Program (MADDSP). This report shows a prevalence of autism spectrum disorder of 3.4 per 1,000 children. However, we believe that this is a minimum prevalence rate for autism spectrum disorder and that most of the cases are probably autism disorder. The monitoring system in Atlanta is dependent upon the review of school records and the milder cases are not likely to be found in these records. In general, the rate is similar to what was found in Brick Township. We cannot determine whether rates are increasing or not because we do not have comparable data from earlier years.

Our system in Atlanta found that there was no difference in the prevalence of autism spectrum disorder by race. It also showed that 68% of children with autism also have mental retardation.

We cannot yet generalize a prevalence for the US population. The population monitored in Brick was very small, less than 9,000 children. The population monitored in Metropolitan Atlanta is much larger, about 290,000 children, but we cannot assume that it is representative of the U.S. population. Determining if there are regional differences in autism prevalence requires data from other regions of the country.

To address the need for state autism monitoring data, in FY 2000 CDC funded four programs in Arizona, South Carolina, Maryland/Delaware, and New Jersey to establish monitoring and tracking programs for autism. Marshall University in West Virginia has a special autism project funded by CDC which also includes collecting prevalence data. At the end of FY 2001, CDC funded 4 Centers of Excellence in Autism and Pervasive Developmental Disabilities Epidemiology for the purpose of collecting and analyzing information on the prevalence and conducting a collaborative epidemiologic case-control study to identify the causes and preventable risk factors for autism. These centers are located in California, Colorado, Pennsylvania, and Maryland/Delaware. The centers will also collect prevalence data because the database provided by the monitoring program will be used to conduct studies of causes and risk factors for autism..

We have established the Alliance for Research in Child Health and Epidemiology, referred to as ARCHE, which includes both state and center partners who are collecting data on autism. ARCHE members are working together to establish a common case definition and methods to identify children with autism so that data from these programs will be uniform and can be combined for accurate national or regional estimates.

With these programs plus the one CDC conducts in Atlanta, we now have 9 states involved in the effort to monitor the prevalence of autism. We have 4 sites already collecting data for a large epidemiologic study to address possible causes of autism, including the role of genetic and environmental factors in the development of autism. With the new funding we received this year, we expect to add at least 3 programs, bringing the total to 12 states who are tracking autism prevalence.

Surveillance for developmental disabilities provides a number challenges including identifying proper sources of information. Unlike birth defects, developmental disabilities may present themselves later in child development. Thus, the sources required for collecting data on these conditions present greater challenges.

Timeline for implementation of IOM recommended research

CDC continues to take a proactive role in addressing vaccine safety concerns. In 2000, CDC and NIH contracted with the Institute of Medicine (IOM) to establish an independent expert committee to review hypotheses about existing and emerging immunization safety concerns. Some researchers have suggested that the receipt of either the MMR vaccine or thimerosal-containing vaccines has been associated with various neurodevelopmental disabilities including autism, attention deficit disorder, language delay, or speech delay. The IOM was asked to review the available scientific information on these issues. CDC has initiated a broad range of studies to better assess these findings as well as to address recommendations made by the Institute of Medicine (IOM) Immunization Safety Review Committee.

MMR and Autism Studies

In the March 2001 IOM report regarding the association between the MMR vaccine and autism spectrum disorder (ASD), the IOM concluded "the evidence favors rejection of a causal relationship at the population level between MMR vaccine and ASD."

The IOM made several recommendations regarding future research including the following epidemiological studies:

1. Explore whether exposure to MMR vaccine is a risk factor for ASD in a small

number of children;

2. Develop targeted investigations of whether or not measles vaccine-strain virus is present in the intestines of some children with ASD;
3. Study the possible effects of different MMR immunization exposures; and
4. Conduct further clinical and epidemiological studies of sufficient rigor to identify risk factors and biological markers of ASD in order to better understand genetic or environmental causes.

CDC is currently funding three research studies that address the above four recommendations from the IOM. The first study, the Metropolitan Atlanta Developmental Disabilities Surveillance Program (MADDSP) MMR/Autism Study, is a large case-control study. The autism cases for the study were identified through MADDSP. The control subjects were selected from the same or similar schools in the Atlanta area and matched to cases based on age and gender. The study is assessing the relationship between the timing of receipt of the first MMR vaccine and risk for developing autism. In addition, several subgroup analyses are being carried out, including analyses using isolated and non-isolated autism cases as well as analyses examining cases with and without pre-existing conditions. The analyses for this study and a manuscript should be completed by early fall 2002.

The second study is the MMR/Regression Autism Study funded by CDC and the National Institutes of Child Health and Human Development (NICHD). This is also a large case-control study that is using a sample of autism cases identified as part of the NICHD 10 Collaborative Programs of Excellence in Autism (CPEA). This study is specifically designed to examine the association between regression autism and the timing of first receipt of the MMR vaccine. The study is being carried out over a three-year period and is designed to test whether or not regressive autism is triggered by receipt of the MMR vaccine. Results from this study are expected in the spring of 2004.

The third study, the Denmark MMR/Autism Study, is a recent study that was carried out in Denmark in collaboration with CDC. The study was designed to follow-up on approximately 537,000 children born in Denmark during the period from January 1, 1991 to December 31, 1998. Of these, 82% received MMR vaccine. The cohort was generated based on data obtained from the Danish Civil Registration System (CRS) and subsequently linked with other national registries. The manuscript is expected to be submitted for publication in 2002.

Finally, CDC is in the early stages of planning a study to investigate whether or not measles vaccine-strain virus is present in the intestines of some children with ASD.
Reports dealing with the findings of measles virus sequences in intestinal biopsies from children with autistic disorder have raised some concern. To resolve differences in previous studies that may have occurred due to study design, sampling biases, and differences in laboratory assays used and in assay sensitivity, an independent, multicenter study is being designed. This study plan is to determine the prevalence of measles virus vaccine strain gene sequences in bowel

biopsy tissue from children with gastrointestinal tract complaints with and without autistic disorder. The study would be designed to ensure use of standardized clinical and laboratory protocols, appropriate enrollment of controls, blinding of specimens, use of standardized laboratory reagents and assays, and appropriate statistical evaluation.

Thimerosal and Neurodevelopmental Delay Studies

In October 2001, the IOM Immunization Safety Review Committee published a report on the possible association between thimerosal-containing vaccines and neurodevelopmental disorders. In this report, the IOM concluded "that the evidence is inadequate to accept or reject a causal relationship between exposure to thimerosal from vaccines and the neurodevelopmental disorders of autism, ADHD, and speech or language delay." Of course, ADHD is attention deficit hyperactively disorder. The IOM made several recommendations regarding future research studies including the following epidemiological studies:

1. Case-control studies examining the potential link between neurodevelopmental disorders and thimerosal-containing vaccines
2. Further analysis of neurodevelopmental outcomes in several cohorts of children outside the U.S. who participated in clinical trial of DTaP vaccine
3. Conducting epidemiological studies that compare the incidence and prevalence of neurodevelopmental disorders before and after the removal of thimerosal from vaccines

CDC has undertaken several studies that address these recommendations. The first study, the Thimerosal Screening Analysis, is an ongoing study that was started in the fall of 1999. CDC used the large automated databases that link vaccination and International Classification of Disease codes (ICD-9) stored in the medical records in the Vaccine Safety Datalink (VSD) project, to screen for possible associations between exposure to thimerosal-containing vaccines and a variety of neurologic and developmental problems. In the first phase of this study, the CDC used data from 2 of the managed care organizations within the VSD, and CDC and VSD researchers found statistically significant associations between thimerosal and several neurodevelopmental disorders, including language delays, speech delays, ADHD, unspecified developmental delays, stuttering, sleep disorders, emotional disorders, and tics. However, the associations were not consistent between the two HMOs. In the second phase of the investigation, CDC investigators examined data from a third managed care organization. Analyses of these data using the same methods as the first study did not confirm results for speech or language delay and attention deficit disorder. The data were not available to study tics or other unspecified developmental delays. A statistically significant relationship between autism and thimerosal was not found in either the preliminary study or the later, larger analysis. This study will be submitted for publication in 2002.

The second study is the Thimerosal Follow-Up Study, which is being designed to assess whether preliminary results from automated data used in the Thimerosal Screening Analysis can be confirmed using objective neuropsychological testing. The study will focus on the conditions found in the first screening analyses, including language and speech delays and ADHD. The design of the new study will address the main drawback of the Thimerosal Screening Analysis, which was that children were not objectively assessed on the neurodevelopmental disorders of interest. The various VSD HMOs categorize neurodevelopmental disabilities in different ways, provide different services for these disorders, and often refer children out of the health care network when they are identified with these particular disorders. Therefore, the Thimerosal Follow-Up Study is planned to examine approximately 1200 children between the ages of 7 and 9 years of age randomly selected from four VSD HMOs based on thimerosal exposure during the first 3 months of life. All 1200 children will be brought into their respective HMOs and will be assessed using a standardized set of neuropsychological test batteries. The preliminary proposal for this study was presented to a panel of external consultants including a consumer representative in March of 2001. In September of 2001, CDC awarded a contract to Abt Associates Inc. to carry out the planning phase of the study. The panel of external consultants continues to provide individual input into the study design and the planning phase should be completed by June 2002. Data collection is expected to begin in the latter half of 2002. Abt Associates Inc. is expected to present the results of the study by the end of 2003.

Several additional studies are being planned to address additional concerns raised by the IOM.

The Thimerosal/Autism Study is planned to be a case-control study to be conducted simultaneously with the Thimerosal Follow-up Study. Autism cases identified through review of automated medical records will be assessed objectively by using a standardized autism assessment tool. Controls will be selected from the Thimerosal Follow-up Study and matched to cases by age and sex.

Two other studies being planned will examine changes over time in the diagnosis of neurodevelopmental delays including autism. These studies will use inpatient and outpatient discharge diagnoses to compare rates of these conditions over time with changes in levels of thimerosal in recommended childhood vaccines. Because recommendations for the removal of thimerosal from vaccines did not occur until 1999, several years of data following the removal of thimerosal will be necessary before these comparisons can be made. Thus, results will not be available until 2005 or later.

CDC funding for autism research from FY 1999 through FY 2004

The CDC spent the following amounts on autism research: $943,000 in FY 1999, $2.6 million in FY 2000, $8.3 million in FY 2001, and plans to spend $11.3 million in FY 2002 and $10.2 million in FY 2003. Plans for FY 2004 have not yet been developed.

Conclusion

CDC remains committed to collecting accurate data on prevalence of autism and conducting studies to find causes of autism. Research is already underway, and more is planned, to look at the relationship between the MMR vaccine and autism. We want each child to be born healthy and to grow and develop normally, so that they are able to lead productive lives. We are dedicated to finding the answer to what causes autism and how it can be prevented. We will continue our work until the answer is known.

Thank you for the opportunity to tell you about CDC's efforts on autism. At this time, I would be happy to answer your questions.

Dr. WELDON. Thank you very much, Dr. Boyle. We will now hear from Dr. Foote. You may proceed.

Dr. FOOTE. Dr. Weldon, members of the committee, I am Dr. Steve Foote, Director of the National Institute of Mental Health's Division of Neuroscience and Basic Behavioral Science. Entering on cue is Dr. Ann Willoughby, Director of the Center for Research for Mothers and Children at the National Institute of Child Health and Human Development, who is accompanying me today.

The sustained attention that this committee has directed to the issue of autism research has helped to focus and accelerate our efforts at NIH. I appreciate the opportunity to talk with you about NIH support of research on autism. I am a neuroscientist who has been interested in the brain and its disorders throughout my career. Like others, I have found autism to be a particularly challenging mystery.

My view of this disorder has been broadened and deepened recently by my continuing interactions with family members of children and adults with autism. I feel their urgency. An affected child cannot wait for research before growing up. Each day, each potential improvement is crucial.

I would like to acknowledge the important role of family and advocacy groups in our efforts. They have not only raised the visibility of autism and challenged assumptions, they have pushed for accelerated and expanded research activities.

Today I would like to report on progress that has been made at NIH. Only a few years ago research on pervasive developmental disorders, the autism spectrum disorders, was fragmented and distributed across NIH institutes and other agencies with little coordination. Today a more integrated, but still appropriately specialized approach is in place.

The basic research on autism that is sorely needed is moving forward at an accelerated pace, as is continued genetic research and studies of the etiology of various symptoms, such as communication disorders. I am a witness today because I play several roles in this integration and overall comprehensive planning. I am the Interim Executive Secretary of the Department of Health and Human Services' Interagency Autism Coordinating Committee that was created under a provision of the Children's Health Act of 2000. In addition, I serve as a scientific program staff member of the NIH Autism Coordinating Committee, a longstanding body that serves to coordinate research efforts within the NIH.

We have made much progress in implementing the provisions of the Children's Health Act of 2000 that focused on NIH research activities. The act authorized augmentation of autism research activities at the National Institutes of Health and the CDC.

First, with regard to the Interagency Autism Coordinating Committee, the Secretary of the Department of Health and Human Services delegated to NIH the authority to organize the IACC, and NIMH was asked to lead this effort. The IACC has already begun to enhance communication and effective interaction among the several agencies that support or conduct autism-related research, service, or educational activities, and it will engage family and advocacy groups.

The NIH Autism Coordinating Committee has continued to act within NIH to allow program scientists and directors of the relevant institutes to come together to plan and conduct research, and it communicates closely with the IACC. The inaugural meeting of the IACC was held in November 2001 on the NIH campus, and it included the public members selected by the Secretary. Lee Grossman, for example, was one of the founding public members of that committee. The date of the second meeting has been set for next month, and we are on schedule, as stipulated in the Children's Health Act, to have twice-a-year meetings of that committee.

In terms of accelerated and expanded research activities, NIH issued a Request for Applications to implement on a fast track the requirement for new Centers of Excellence Programs for autism research as specified in the Children's Health Act. An RFA is a clear statement to the field, setting aside funds, that NIH invites research applications in a particular area. These comprehensive centers are to be called STAART Centers, which stands for Studies to Advance Autism Research and Treatment.

A number of applications were received in response to this initial RFA. They were reviewed last month, and the successful applicants will be funded this summer. A second round of competition has already been posted. It will close in August of this year, and those successful applicants will be funded in 2003. At that time the full network of at least five centers stipulated by the law will be in place. The five participating NIH institutes have established a funding pool of $12 million per year.

This past year the NIH ACC also endorsed two other RFAs, one for groups planning to submit center applications this year in order to allow them to undertake planning activities, and one for innovative research into treatments for autism.

In addition to these activities, NICHD and NIDCD will competitively renew their longstanding Cooperative Program for Excellence in Autism. This program will expand to be essentially the same size as the STAART program. And in yet another enhancement of the NIH autism research portfolio, NIEHS, in collaboration with the EPA, has funded two new centers focused on autism research.

We at NIH are in a heightened state of awareness concerning the need for more research on autism, due to the clear magnitude of this major public health problem and due to the work of many people within and outside this room, and we have been making progress. As mentioned earlier, our budget for autism research has expanded rapidly over the past few years, more than doubling. The research now in this portfolio, and to be included in the near future, holds the promise of answers not only for children with autism, but also for unlocking the secrets of brain development, what its possibilities are, how it goes wrong, and when to intervene, which will help all children realize their potential.

In summary, NIH is on schedule in terms of implementing the letter and the spirit of all aspects of Title I of the Children's Health Act, including a broadly based increase in autism research support, the initiation of a new Centers of Excellence Program, the extension of the CPEA Program, the enhancement of genetic and other resources, and the establishment of the Interagency Autism Coordinating Committee.

I would be happy to answer any questions.

[The prepared statement of Dr. Foote follows:]

Testimony
Before the Committee on Government Reform
United States House of Representatives

NIH Autism Research Efforts

Statement of

Stephen L. Foote, Ph.D.

Director,
Division of Neuroscience and Basic Behavioral Science,
National Institute of Mental Health,
National Institutes of Health,
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 1:00pm
on Thursday, April 18, 2002

Good afternoon, I am Dr. Steve Foote, the Director of the Division of Neuroscience and Basic Behavioral Science at the National Institute of Mental Health (NIMH), a component of the National Institutes of Health (NIH). Also, currently I serve as the interim Executive Secretary of the Department of Health and Human Services (HHS), Interagency Autism Coordinating Committee (IACC) created under a provision of the Children's Health Act of 2000. I am also a member of the NIH's long-standing Autism Coordinating Committee (NIH/ACC). Today, I am accompanied by Anne Willoughby, M.D., M.P.H., Director of the Center for Research for Mothers and Children at the National Institute for Child Health and Human Development at the NIH.

Thank you for the opportunity to participate in this important and timely hearing on autism, a disorder that causes so much pain for too many families. The NIH is genuinely appreciative of the sustained attention that this committee has directed to the issue of autism research and I thank the Committee for its interest in the topic.

Current estimates indicate large increases in recent years in the numbers of individuals being diagnosed and receiving public services for autism spectrum disorders. Autism is a complex neurobiological disorder that persists throughout a person's lifetime, impairs ability to communicate and to relate to others, and is often associated with rigid routines or repetitive behaviors such as obsessively following schedules or arranging belongings in very specific ways. Current surveys show that autism occurs in all racial, ethnic, and social groups. Autism is heartbreaking, not only for the affected individual, but also for the impacted family. Families coping with this devastating illness are searching for answers about its causes, diagnosis, prevention, and treatment. Presently, there is no effective means to prevent the disorder, no fully effective treatment, and no cure. Research indicates that early intervention is critical for children with autism to gain maximum benefit from current therapies.

NIH has a long history of funding research on autism. Within NIH, five institutes are members of the NIH Autism Coordinating Committee (NIH/ACC), a long-standing internal body made up of all of the institutes that are conducting autism-related research. Members of the NIH/ACC include NIMH, the National Institute of Child Health and Human Development (NICHD), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute on Deafness and Other Communication Disorders (NIDCD), and the National Institute of Environmental Health Sciences (NIEHS). In addition, a staff representative from the National Institute of Allergy and Infectious Diseases participates in NIH/ACC meetings. The NIH/ACC functions in a coordinating role for autism research activities funded and conducted by the NIH Institutes. Representatives from the NIH/ACC attend meetings of the IACC and conduct liaison activities between the two committees to ensure that IACC concerns and issues are addressed by NIH program staff. The NIMH and NICHD Directors, as co-chairs, provide oversight for NIH/ACC activities. Because NIMH has been designated to lead the implementation of the IACC, the NIMH Director also serves as chair of the IACC.

The main message of my testimony today is that the NIH has made substantial progress since the enactment of the Children's Health Act in further expanding and intensifying our autism research activities, and is on schedule for meeting the other responsibilities assigned to it through the Act.

The Children's Health Act of 2000, P.L. 106-310, signed into law on October 17, 2000, authorized the Secretary of HHS to conduct additional activities relevant to autism and pervasive developmental disorders, including expansion, intensification, and coordination of activities of the NIH with respect to research on autism; developmental disabilities surveillance and research programs; expanded information and education activities; and, establishment of an Interagency Autism Coordinating Committee. The Act also requires that an annual report be prepared and submitted to the Congress. The Secretary submitted the first such annual report in mid-2001, and the second annual report last month. The report summarizes the scope and intensity of autism-related activities across the DHHS. My testimony will summarize and clarify the information within that comprehensive report.

RESEARCH

Over the past few years, NIH has expanded autism research considerably and enhanced its coordination. The amount of NIH funding for autism research grew from $22 million in FY 1997 to $56 million in FY 2001. Specifically, the NIH spent the following amounts on autism research: $40 million in FY 1999, $52 million in FY 2000, $56 million in FY 2001, and plans to spend $65 million in FY 2002. In FY 2003, the President's Budget includes $70 million for autism funding. Plans for FY 2004 have not yet been developed. Thus, NIH is committed to the broad intensification of autism research efforts called for in the Act. This effort encompasses a large number of grants, contracts, and intramural research programs distributed across the NIH. From this broad spectrum of research activities, I have chosen a select few to emphasize today.

Behavioral Interventions Research

All of the NIH/ACC institutes conduct and fund behavioral research. Research to develop and test behavioral (i.e., psychosocial as opposed to pharmacological or biomedical) interventions for children with autism is an essential part of NIH's efforts to expand research programs in autism. At NIMH alone, funding devoted to testing psychosocial preventive and treatment interventions accounts for about three-fourths of the entire budget of the branch devoted to child and adolescent treatment and preventive intervention research. In 2001, of 18 funded grants in this branch, 14 involve research on psychosocial interventions. Behavioral interventions research in autism has also been expanded. In November 1999, a major workshop on treatment of autism was organized by the NIH/ACC and the U.S. Department of Education. A prominent part of the meeting was devoted to intensive behavioral and psychoeducational treatment in autism. The proceedings of the meeting were published in the *Journal of Autism and Developmental Disorders* (October 2000 issue), and the first three reports are entirely focused on behavioral research. In 2001, the NIH/ACC published a Request for Applications (RFA) with dedicated funding for "Development of Innovative Treatment Approaches to Autism" (MH-01-101). This initiative grew out of the 1999 meeting. As a result of this RFA, NIH awarded seven grants to institutions across the country in September 2001 to support the development and/or refinement of treatments for core and secondary symptoms of autism. Three of these grants focused on behavioral/psychosocial treatment approaches. The grants were funded through the NIH/ACC, with four Institutes contributing funds: NIMH, NICHD, NINDS, and NIDCD. The grants are for three years each, totaling $2.9 million dollars over the three years. The funded grants address psychosocial treatments for teaching speech, imitation, and joint attention skills; psychopharmacology for behavioral problems, emotional dysregulation, and cognitive deficits; and testing of an animal model of self-injurious behavior. Currently in the planning stages is a follow-up workshop for investigators, which will focus on progress in the field since the 1999 meeting. Methodological issues related to conducting behavioral and psychosocial interventions for children with autism, and potential solutions to barriers to conducting this research will be addressed. The workshop is being planned for the fall of 2002.

In addition to supporting the development of new and innovative treatments, NIH is also supporting research focused on studying the efficacy and safety of treatment interventions that are promising and that are commonly used in the community without adequate testing, or that are aimed at specific impairing symptoms such as compulsions, stereotypies, overactivity, and self-injurious and aggressive behavior. Both psychosocial and pharmacological interventions are being studied. Included in the research on psychosocial treatments, NIMH is currently supporting studies to test the effectiveness of a parent-delivered technique to teach joint attention skills, the use of visual stimuli to teach language to nonverbal children, and the impact on parents of involvement in an intensive parent training early intervention program. Similarly, NICHD is supporting work on treatment interventions through its Collaborative Programs of Excellence and several other research projects.

Medications trials in autism are ongoing in the autism Research Units on Pediatric Psychopharmacology (RUPP), a research network supported by NIMH contracts and devoted to testing promising pharmacological agents for the treatment of children and adolescents with autism and other pervasive developmental disorders.

The NICHD/NIDCD Network on the Neurobiology and Genetics of Autism

The NICHD/NIDCD Network on the Neurobiology and Genetics of Autism consists of 10 Collaborative Programs of Excellence in Autism (CPEAs) that link together more than 75 researchers in 26 universities and more than 2500 families of people with autism. This Network requires each CPEA both to conduct a cohesive, site-specific, multidisciplinary research program on the causes, brain structure and function, and clinical development in autism disorders and to participate in some trans-Network collaborative studies that no one project has the needed expertise and/or subject population to investigate individually. The CPEA Network is in turn linked to a six-nation European autism consortium. The CPEA Network is now studying the world's largest group of well-diagnosed people with autism for whom both genotype and extensive phenotype data will be available. In addition, because of their combined clinical and scientific resources, the CPEAs address urgent public health questions when appropriate, including the study of the neuropeptide secretin for treatment of autism and the study of regression or late onset autism. In November 2001, the results of another CPEA study on secretin were published, finding that patients with autism who received a form of secretin showed no statistically significant improvements in the core symptoms of the disorder when compared to those same patients receiving a placebo. NIH has solicited applications from CPEA sites for an additional 5 years of funding; these applications are currently undergoing competitive peer review. In addition, NIH will establish a data-coordinating center, designed specifically to expedite and maximize analysis of the data generated by the CPEA research projects and, where appropriate, other NIH-supported research activities. The NICHD and NIDCD plan to allocate $60 million over the next five-year period to sustain and enhance the CPEAs.

The NICHD/CDC Study on the Relationship between Autism and Vaccines

The NICHD and CDC are co-sponsoring a study of the possible association of symptoms of regressive autism with measles, mumps, and rubella (MMR) vaccinations. Regressive autism involves a relatively rapid onset of loss of a child's skills, typically involving loss of speech or words, but can include changes in social behavior or the onset of repetitive behaviors that can interfere with development. Regressive autism usually occurs during the second year of life. Among children diagnosed with autism, it is estimated that between 20-39 percent experienced regressive autism. The remainder of these children experience a more gradual development of symptoms related to autism. The MMR study, which began in September 2000, is examining the medical and developmental records of 1,600 well-diagnosed cases of autism (including regressive and non-regressive) and a large number of healthy controls to assess whether there is a temporal relation between receipt of the MMR vaccine (and possibly other vaccines) and the beginning of symptoms in early onset autism and regressive autism. The next phase of the study will use laboratory tests to assess the levels of measles antibody titers and to search for evidence of persistent measles infection in blood that could be attributed to the MMR vaccine in early onset and regressive autism cases and matched controls. Data have been collected on regressive vs. nonregressive autism at all of the CPEA sites. Those data are undergoing analysis; they are necessary to establish whether regressive autism differs from nonregressive autism, and along what dimensions, to ensure scientifically valid comparisons to normal controls.

Children's Centers for Environmental Health and Disease Prevention

The National Institute of Environmental Health Sciences (NIEHS) and the Environmental Protection Agency (EPA) have funded two new Children's Centers for Environmental Health and Disease Prevention that will focus research on potential environmental factors that may be related to autism. The centers each have been funded at $5 million, or approximately $1 million per year for five years beginning in August 2001. The new Children's Center at the University of California at Davis (UC Davis) will investigate how environmental risk factors may contribute to childhood autism. There has been speculation among both parents and health professionals that prenatal or early postnatal exposure to various metals or chemicals or even vaccines may trigger autism. To help address this concern, the Center's research will include a large case-control epidemiological study of various exposures and the development of autism. This Center will also conduct research to develop new animal models for studying social interaction and the impact of neurotoxicants on social behavior. Additional studies will focus on elucidating the cellular and molecular mechanisms by which specific neurotoxicants can perturb critical neuronal functions during development. The team of investigators will include scientists from the NIEHS Environmental Health Sciences Center at UC Davis and the NIEHS Superfund Basic Research program, also at UC Davis. The work will be carried out within the infrastructure of the UC Davis M.I.N.D. (Medical Investigation of Neurodevelopmental Disorders) Institute, which has a strong relationship with the autism advocacy community.

The newly funded Children's Center at the Robert Wood Johnson Medical School of the University of Medicine and Dentistry of New Jersey will seek to determine the possible influence of mercury, lead, and valproic acid (a drug commonly used to control seizures) on autism, learning disabilities, and regression. Studies to be conducted will look at critical windows for brain development in the forebrain and hindbrain and will attempt to link exposures or disturbances at these times to subsequent behavior. Researchers also will look for differences in genetic susceptibility of children to environmental toxicants. Researchers will use brain imaging to determine whether children with higher exposures to environmental toxicants have different patterns of brain growth and development.

Centers of Excellence

The Children's Health Act of 2000 also called for NIH to establish at least five Centers of Excellence in Autism Research. NIH took several steps in 2001 to begin implementing a program that will meet all of the specifications of the Act regarding the organization, scientific goals, and other activities of these centers.

To help interested groups of investigators prepare to submit high-quality applications to become autism centers, the NIH issued an RFA on "Developmental Grants for Autism Centers of Excellence" (see http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-01-013.html). The NIH/ACC institutes jointly sponsored the RFA which was issued in April 2001 and was designed to provide developmental grants to teams of investigators to enhance their ability to plan, organize, and demonstrate the feasibility of their autism research efforts as they prepared applications for comprehensive center support over the following year. Through this method, NIH sought to optimize the chances that investigators who want to do research on autism would be successful in the highly competitive NIH peer review process. Each award under this RFA was for one year and a maximum of $100,000 for direct costs ($125,000 if multiple institutions were involved; thus, the total cost--direct costs and facilities and administration costs--of each grant would range from about $150,000 to $175,000). NIH anticipates that the developmental grants RFA will be a one-time solicitation. These developmental grants were intended for investigators who will submit grant applications later (by an August 2002 deadline) to support full autism centers of excellence. Six developmental grants were awarded by the targeted funding date of October 1, 2001.

NIH also implemented a parallel funding initiative intended for applicants who wished to apply immediately for full autism center of excellence support on an earlier timeline, without participating in the developmental grant process. To this end, NIH released, in mid-June 2001, an RFA (see http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-02-001.html) that formally solicited proposals for comprehensive centers of excellence in autism research. These comprehensive centers will be called STAART (Studies to Advance Autism Research and Treatment) Centers. The RFA had a deadline for applications of November 29, 2001, and a number of applications were received. These applications underwent peer review in March 2002, and NIH anticipates beginning funding of successful STAART applications from this first round of competition in June 2002, with contributions from the NIMH, NICHD, NINDS, NIDCD and NIEHS. In addition, researchers who unsuccessfully applied for developmental grants or comprehensive center grants may submit a revised application for STAART center support by the August 2002 deadline. New applicants also may apply for STAART center support. Thus, applicants could compete for STAART support in one of three ways: (1) applying for a developmental grant in July 2001, with the intention of then applying for a comprehensive center grant in August 2002; (2) applying for a comprehensive center grant in November 2001, with the option to re-apply in August 2002 if unsuccessful; or (3) applying for a comprehensive center grant in August 2002.

NIH estimates that the total funds (direct costs and facilities and administration costs) available to support the STAART Centers Program when it is fully established in FY2003 will be $12 million per year. NIH will use this amount to fund the complement of at least five centers, a data coordination center, and collaborative projects among the centers. The Steering Committee of the STAART Centers Program will determine the exact nature of the cooperative studies.

Facilitation of Research

NIH has undertaken several activities to increase the quality and availability of genetic and tissue resources to the autism research community. The NIMH Genetics Repository has expanded its activities in the domain of collecting blood samples, creating cell lines, and distributing genetic materials to be used in autism research. This is a national resource that collects, stores, and distributes such materials very broadly across the scientific community. NIMH has also worked with a genetics data bank supported by an autism advocacy group, which resulted in a grant application that received high marks in peer review and has now been funded. This grant will support the continued activities of the genetic data bank, a resource that distributes genetic materials broadly to the autism research community. Also, NIH structured the RFA for the STAART Centers Program so that these centers, when funded, will become a national resource for genetics studies, greatly expanding available resources. The CPEA program also will continue its ongoing, extensive activities in the collection of genetic data within its research network. The NINDS continues to support promising research in the genetics of autism, including increased support for the development and expansion of genetics resources.

NIH Institutes have continued and expanded their support of existing tissue collection and distribution resources at several sites. Postmortem brain tissue offers a unique, high-resolution window into the inner workings of brain cells. Only with access to brain tissue can researchers uncover the underlying neuropathology of autism. NIH currently supports ongoing efforts at four tissue banks around the country to collect and make this vital resource available to researchers. Recently, NICHD awarded special supplements to target the acquisition of necessary biologic materials from individuals with autism for focused study. In addition, NIMH has just undertaken a funding initiative to enhance activities in this arena for several disorders, including autism. NIH also anticipates that the STAART Centers Program will provide resources for tissue-based research in autism.

Pblic Input

The NIH is committed to bringing public views to our activities, programs, and decision-making; to conveying information about NIH to a broad public; and to seeking comment about our efforts and help evaluating our performance. NIH offers many opportunities for public participation, including the NIH Director's Council of Public Representatives meetings, the individual Institute council meetings (every institute has public members on its Advisory Council), and specially conducted public forums around the country. In addition, some Institutes solicit public participant reviewers on Scientific Review Groups for treatment and services research grant applications. NIMH also widely disseminated an invitation with nomination procedures to patients, consumers, family members, service providers, policymakers, and educators regarding serving as public participants. NIMH staff reviewed the nominations and chose public participants after a rigorous review process. Members of the autism advocacy community are among the public participants currently serving and offering highly relevant consumer perspectives on NIMH scientific review committees. The commitment to involving the public is being carried over to NIH's newest activities - the review groups for both the STAART Centers and the CPEAs included members of the public.

For the last two years, NIH has held a special meeting with members of the autism advocacy community to exchange information. As a result of the first meeting, NINDS developed a listserv (now maintained by NIMH) of the e-mail addresses of advocacy group members, which continues to update those who register with news of interest to the autism community. Also, the National Library of Medicine's Medline Plus website for autism became a significant topic of discussion and increased effort in response to the autism parents meeting last year (http://medlineplus.nlm.nih.gov/medlineplus/autism.html). This is a searchable site with numerous links. It provides the latest news, information about research (with the ability to do a Medline search of the relevant scientific literature), names of autism advocacy organizations, information on rehabilitation and treatment, news on specific conditions such as Asperger's, information on related issues such as vaccines (with a link to the CDC), and links to the specific NIH/ACC Institutes:

http://www.nimh.nih.gov/publicat/autism.cfm
http://www.nichd.nih.gov/autism/
http://www.ninds.nih.gov/health_and_medical/disorders/autismshortdoc.htm
http://www.nidcd.nih.gov/health/pubs_vsl/autism.htm

Interagency Autism Coordinating Committee (IACC)

The Children's Health Act of 2000 established the IACC. Secretary Tommy Thompson delegated the authority to establish the IACC to the NIH in April 2001; NIH subsequently asked NIMH to take the lead for coordinating the activity of this important committee, whose primary mission is to facilitate the effective and efficient exchange of information on autism activities among the relevant government agencies and with advocacy and other groups focused on autism and related disorders, and to coordinate autism-related activities.

The Children's Health Act also permits the Secretary to appoint parents or legal guardians of individuals with autism or other pervasive developmental disorders to the Committee. Such appointments are necessary and vital to the conduct of the Committee's mission. In particular, public members of the IACC will bring to DHHS and its member agencies the concerns and interests of members of the autism community. This kind of interactive, two-way communication is critical. The IACC serves as a forum and helps to increase public understanding of the member agencies' activities, programs, policies, and research, brings important matters of interest forward for discussion, and ensures that the voices of the parents and others advocating for those with autism are clearly heard. The Secretary appointed four public members.

Governmental agencies represented include the following: NIH/ACC members (NIMH, NICHD, NIDCD, NIEHS, and NINDS), CDC [the National Center on Birth Defects and Developmental Disabilities], the Administration for Children and Families [(ACF) the Administration on Developmental Disabilities], the Food and Drug Administration (FDA), the Agency for Toxic Substances and Disease Registry (ATSDR), Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Department of Education.

In November 2001, the inaugural meeting of the IACC was held on the NIH campus and included the public members selected by the Secretary of HHS. A summary of the first meeting is posted on the NIMH Web site (see http://www.nimh.nih.gov/events/interagencyautism.cfm). The date of the second meeting, May 24, 2002, has been set. The IACC is on schedule to meet twice a year as set forth in the Act.

Report to Congress

Section 105 of the Act requires the Secretary of HHS to submit an annual report to Congress "concerning the implementation of this title and the amendments made by this title." The first annual report was submitted in July 2001. The second annual report was signed by the Secretary on March 12, 2002 and submitted to Members of Congress.

Current Activities

The NIH/ACC institutes are currently implementing the STAART Centers Program, competitively renewing the CPEA program, and implementing the activities of the IACC. I have described several other ongoing activities with respect to further research on vaccines and their possible relationship to autism. Enhancing the quality and coordination of autism research activities across the NIH and with other Federal Agencies—in a way that is open and readily discernable by Congress, members of parent groups and other interested organizations--remains of the highest priority. That concludes my prepared remarks. I would be happy to answer any questions.

Mr. BURTON. Thank you, Dr. Foote. Dr. Willoughby, does she have any comments?

Dr. WILLOUGHBY. No, sir.

Mr. BURTON. You are just there to hold him up if he falls down. [Laughter.]

Dr. WILLOUGHBY. He doesn't need it.

Mr. BURTON. OK. I would like to put a chart up there. Maybe you can explain this to me. The chart on the comparisons, please, the NIH one. Yes.

I don't know if you can see that. Do you have a slide that you can put it on the slide machine, so that they can maybe see it clearly?

What that says is that, for diabetes, the yellow line on diabetes shows for fiscal year 2003 there's $845 million; in fiscal year 2002, the blue line, it is $781.3 million, and in fiscal year 2001, it is $688.1 million.

If you look at the middle set of lines, that concerns HIV and AIDS. There is $2,770,000,000 in fiscal year 2003; $2,000,515,000 in fiscal year 2002, and $2,247,000,000 in fiscal year 2001.

Then that very last part that is very difficult to see, that shows autism. In 2003 it will be $70 million, and in 2002 it will be $65 million, and in fiscal year 2001 it is $56 million.

Now, according to the statistical data we have, there is about the same number of people who are autistic estimated as there are HIV, and yet the amount of money that is projected to be spent for HIV is going to be almost $3 billion as opposed to $70 million for research. Can you explain that to me? Any of you?

Dr. FOOTE. Well, I think you know better than I do that these budget figures result from a complex state of affairs that involves not only NIH, but Congress, public health issues, and history. I don't think that I could adequately explain exactly how those numbers came about.

Mr. BURTON. Well, NIH, as I understand, they come up to the Hill and they propose to the appropriators, the Appropriations subcommittees, "The College of Cardinals" we call them up here, they propose various amounts of spending or spending levels for various things. Can you tell me, in the last 2 or 3 years, how much money has been requested for AIDS research or for diabetes research or for autism research?

Dr. FOOTE. The short answer is no.

Mr. BURTON. Well, could you get that for me?

Dr. FOOTE. Yes.

Mr. BURTON. I would like to know what NIH is asking for.

Dr. FOOTE. We can obtain that information for you.

Mr. BURTON. Now NIH receives unprogrammed, unallocated funds for research, and I don't, how much is that? Do you know how much money that is? Well, it is in the billions of dollars. Can you tell us how the research spending levels are decided over there, the unspecified, unprogrammed moneys?

Dr. FOOTE. Yes. NIH has several approaches to funding research. One of the largest is to accept investigator-initiated grant proposals, which are subjected to peer review. Priority scores are assigned, and then program officials like myself make final funding decisions and budgetary decisions.

There's a distribution of funds among basic research funding pools, basic research that is applicable to biomedical research. This issue has come up earlier today. For example, as one of the earlier witnesses pointed out, in an area that is relevant to autism, we support a number of studies of brain development, imaging the brain in children, activities that are relevant to understanding childhood disorders like autism or attention deficit hyperactivity disorder. A certain fraction of our funds goes into those basic research efforts. There are other funds that are dedicated, in the case of clinical neuroscience, to efforts to understand specifically brain development in individuals affected with autism, and so forth.

Mr. BURTON. Let me interrupt just a minute here. The NIH estimates that now 1 in 250 children born will become autistic between the ages of 3 and 8, I believe. Now that is your estimate. That is NIH's estimate. That is an epidemic. That is a major, major problem, and yet only $70 million is going to be allocated for research in this area in 2003, and only—what did I say—$65 million this fiscal year. I would suggest that it might be wise to take a look at those unallocated funds and see if more of that couldn't be appropriated or utilized for autism research.

The other thing I want to point out to you, and you were here, you have been here for the whole hearing. I am sorry you had to wait so long, but they always take longer than we anticipate, especially when we have votes.

I want you to look around. Everybody that has a child who became autistic shortly after being vaccinated, hold your hands up, please. I want you to look at that. Do you see that? I didn't put them up to that. But every time we have a hearing—and, incidentally, I will hold my hand up, too, because my grandson was a perfectly normal child, was going to be 6-foot 10. I was planning on him in the NBA to take care of me in my old age. Within just days after getting nine shots in 1 day he was banging his head against the wall and running around the wall.

And all these people tell you pretty much the same thing. Yet, when we have people from NIH and CDC up here, they continue to tell us, well, we don't have any information or evidence that these vaccines have anything to do with it. Hold your hands up again, will you, please?

[Significant show of hands.]

Mr. BURTON. I want you to look at that. Now I don't know what you want for evidence, but that ought to be enough to make sure that there is very comprehensive studies done on thimerosal, which has mercury in it, that is going into so many children's vaccines. Now, granted, you are taking it out.

You have been up here before, I believe, but I have also mentioned that every Congressman who gets a flu shot gets thimerosal, too. I told the doctor today, Dr. Eisold, the physician here on Capitol Hill, that I am going to inform every single Congressman and Congresswoman and Senator before the next shots are given for flu vaccine that they have mercury being injected into their bodies. Now we all want to get the flu shot, obviously, because we don't want to have that confused with anthrax and maybe die or something, because the anthrax scare was a real one, and the symptoms are similar. But we want to make sure that everybody is informed about it.

I tell you, most people who had their children vaccinated did not know that they were being injected with mercury. I mentioned earlier I think five or six countries that have stopped using thimerosal in their vaccines, and I read a letter from this Russian doctor who says there is no doubt that it has a bad effect on children who are being vaccinated. Yet, we continue to put mercury into these children, not in one vaccine, but in my grandson's case, I think it was seven or eight of the nine in 1 day.

So I would urge you, and you will be getting a letter from me and the head of the Autism Conference. We will be sending you letters signed by probably 50 or 100 Congressman urging you to do more extensive research into the vaccines and into the causes of autism in the coming years. We're also going to be contacting the members of the Appropriations Committee to try to earmark funds for that, and the people in the audience are going to be contacting everybody they know that lives and breathes to write to their Congressmen and Senators about it as well.

[Applause.]

Mr. BURTON. Thank you. Thank you. I didn't request that, either.

Dr. Weldon, do you have any questions you would like to ask?

Dr. WELDON. Yes, thank you, Mr. Chairman. I have some questions for Dr. Boyle.

Dr. Boyle, you mentioned several studies that the CDC is undertaking in response to the recommendations of the recent IOM. I have several questions regarding those studies.

First of all, as you know, many Americans are suspect over the ability of the CDC to conduct an unbiased study. Rightly or wrongly, these are legitimate concerns. Well, they are concerns, whether you feel it is right or wrong. I certainly hope that those concerns are being taken into account.

If the research you are doing is to have any real effect on public perceptions, you must make every effort to ensure independence. Otherwise, the CDC will have not achieved its desired goal of restoring public confidence in the vaccine program.

Specifically, to get to my questions, the first study you mentioned using the MADDSP data appears to be an epidemiologic study. Is that right? There are no biopsies done as part of that study to look at the presence of measles in the intestinal tracts of these children, correct?

Dr. BOYLE. That is correct.

Dr. WELDON. The second study you mentioned is designed to determine whether or not the timing of the MMR has any association with the onset of regressive autism. Again, this is another epidemiologic study, correct?

Dr. BOYLE. Yes, and, actually, that one is being conducted in conjunction with NIH.

Dr. WELDON. It is? OK. So, again, no biopsy specimens, no tend to look at the gastrointestinal tract.

Dr. FOOTE. There are blood samples to examine questions of excretion and blood levels of mercury and immune parameters.

Dr. WELDON. The third study, I think it is a study out of Denmark, again, an epidemiologic study, but then you mentioned a fourth study?

Dr. BOYLE. Actually, that one also has biological markers in it as well.

Dr. WELDON. The third one?

Dr. BOYLE. The Denmark study.

Dr. WELDON. The Denmark study? Is it serum specimens?

Dr. BOYLE. This is done in collaboration with the Danish National Research Study, and it actually looks at some particular biomarkers.

Dr. WELDON. What are those biomarkers?

Dr. BOYLE. Various neurotropins. There is a study that was reported last year at the hearing by Dr. Cary Nelson at the NIH that looked at some specific neurotropins that may, in fact, be predictors of autism. So what we're trying to do with that study is essentially look at whether or not these particular children may be more vulnerable.

Dr. WELDON. What I really wanted to get though is in the fourth study, you say you are in the early stages of planning this study to investigate whether or not measles vaccine strain virus is present in the intestines of some children with ASD. So is that the one where you are going to try to look at the issues raised by Dr. Wakefield in his reports and Dr. O'Leary?

Ms. WHARTON. There is a study that is still in development. No word has made yet to an investigator to do the study, but, yes, there is a plan to look for the presence of measles virus geno-menotestinal tissue.

Dr. WELDON. One of the concerns that I have is that the biological markers is a competent lab. As I understand it, the standards and the techniques that Dr. O'Leary uses are not in common use in most labs. They are relatively unique and there are only a small handful of labs that are capable of duplicating that work. Is that correct?

Ms. WHARTON. Yes, similar methods to what Dr. O'Leary used were being put in the study, and laboratory work will be done simultaneously on blinded specimens by a number of different independent laboratories.

Dr. WELDON. OK. The question I have for you, are you making every effort to make sure that the virology sampling and analysis is of the same quality and caliber as the work that is done by Dr. O'Leary? I am saying this because, if you publish something and if other scientists can nitpick it and say they didn't use this technique and didn't use that technique, and the techniques were faulty, then we are not going to restore public confidence in the system and we are going to be back to square one.

Ms. WHARTON. Yes, I appreciate that, Dr. Weldon, and thank you for making that point. There will be an effort made in this study to use the best virologic techniques available, as well as having specimens obtained from patients whose clinical systems are well-characterized, whose vaccinations and disease histories are ascertained with appropriate blinding of the specimens.

Dr. WELDON. Thank you very much. I would like to be notified as soon as possible when you are ready to—I guess you do Request for Proposals associated with that study?

Ms. WHARTON. Yes, as far as I know, no specific funding mechanism has yet been identified, but we hope to be able to make an award this fiscal year.

Dr. WELDON. Thank you. Well, please keep my office informed.

Dr. Boyle, the epidemiologic study on thimerosal, the preliminary data, as you know, did not show any link with autism, but did show a statistically significant link with speech development disorder, and then the final analysis that statistically significant link disappeared.

There have been a number of people who have wanted to look at that data, and the CDC has not released the datasets. Could you explain to me why the CDC has not released the datasets on that information? There is some concern that the sampling techniques used may have diluted down the information.

Ms. WHARTON. With your permission, Dr. Weldon, I will respond to that question. There has been a lot of discussion about the differences in the preliminary analyses of the screening data from the Vaccine Safety Data Link with the subsequent studies done.

The major differences between the preliminary analyses were that they included followup through 1997. Because of the way the Vaccine Safety Data Link works, we receive additional information each year regarding subsequent followup on patients. So what has happened since then is we now have several years of additional followup on the children who were initially part of the study cohort, which actually should greatly enhance our ability to detect neurodevelopmental problems which may not be diagnosed until the children are older.

With extension of the study 2 years, from 1997 through 1999, there is an average increase in followup of 23 months. So it is not that we have diluted it out by including younger children, but we have extended followup, and that accounts primarily for the differences in findings between the preliminary analyses and the subsequent analyses.

Regarding your question about access to the information, as you know, the Vaccine Safety Data Link essentially is electronic medical information of a large number of individuals. There is a strong obligation to maintain the confidentiality of those data. That need has greatly complicated the ability to make the information, the dataset, available for independent review.

However, we appreciate this request and have worked very hard with the individual health maintenance organizations that participate in the Vaccine Safety Link Data Project to identify mechanisms through which independent researchers can repeat analyses from these sorts of vaccine safety studies while maintaining the confidential nature of these private medical records, as well as the proprietary interests of the health maintenance organizations that participate in the project.

We have been able to develop a process that is quite comparable to that used by the National Center for Health Statistics, using their Research Data Center, so that a dataset can be made available for re-analysis using a protocol that could be developed by independent researchers. We have shared this plan with Chairman Burton's staff. So, in fact, we have been able to solve, I think, the most serious problems related to re-analysis and will be prepared to receive protocols to——

Dr. WELDON. To release the data?

Ms. WHARTON. It is making the data available for analysis using a protocol that has been written. We can't release the data because these are confidential medical records, but the data can be made available in a secure setting, so that analyses can be performed by independent researchers.

Dr. BOYLE. I just may add as well, this is a prototype that the National Center on Health Statistics has developed for other types of confidential information, allowing people access, allowing them to have availability of the resources to actually analyze the data.

Dr. WELDON. Well, what I would like to see is the data made available as soon as possible, so that an independent review—so that the committee can look at the data. Certainly, I understand the need to maintain patient confidentiality.

One other question I have: Dr. Boyle, you were in my office about 2 years ago. We talked about incidence, and you talked about the Atlanta study. It was just getting underway. So, based on the information you have recently released, the incidence rates that were being spoken of, 1 in 250, 1 in 500, and many scientists were questioning that 2 years ago and 3 years ago, you are saying now, yea, verily, at least in Atlanta that it is that high, and it is reasonable to speculate it may be that high throughout the Nation? I know you are scientists and you are going to say we have no proof of that, but I have been in Atlanta and I have been to lots of other cities. I find it hard to believe that this would be exclusive to Brick Township and Atlanta. So the rates are really high?

Dr. BOYLE. Based on what we found in Atlanta, they are very comparable to what we found in New Jersey. The important part of what we found in Atlanta is that most of, even though we call it autism spectrum disorder, the way we find cases is through access to school records, and we know that most of those children are children who are in special education. Higher-functioning children, children with Asperger's disorder, or children with higher-functioning autism may not be captured by those methods. So, in fact, the rate, if you look at the whole spectrum, might be a little higher.

Dr. WELDON. Well, I know you are scientists and you won't believe it is going to rain unless the weather balloons go up and measure the humidity in the clouds and the barometric pressure, etc., but, and I think I have said this before at previous hearings, when I started medical school in the seventies, I didn't know anybody with autism. I never saw any kids with autism. I didn't know anybody on the faculty with autism. I didn't know, I never saw a case as I went through all the rotations. The thing that has really dramatically struck me is I am starting to hear everywhere so-and-so's got a child with autism. I think it is one of these things where the scientists are the last to find out what is going on.

I am certainly glad your data verified what everybody has been saying, that we've got a crisis, and I certainly would encourage you to duplicate the analysis in other locations and try to refine the data as much as possible, and then continue to track it to see if the rate is increasing even further. I certainly appreciate all the work you are doing.

I yield back to the gentleman from Connecticut.

Thank you very much. Thank you for your testimony.

Mr. SHAYS [assuming Chair]. I thank the gentleman.

I want to apologize. I don't usually take the Chair when I haven't heard the testimony, but Mr. Burton is on the floor of the House on an issue that he also cares deeply about, and as we know, he is a very passionate person, thank goodness.

I want to ask you a question, Mr. Foote. "Doctor," I'm sorry. I just want to ask you, do you think the title of this hearing is appropriate in terms of its being an epidemic or would you qualify it in a certain way, and if you would qualify it, how would you qualify it? It is not a trick question. It sounds like it, but, honestly, it isn't.

Dr. FOOTE. I think it is clear, as Dr. Weldon was saying, that there has been a change. It has been a change that has involved a substantial increase, as in Chairman Burton's definition of an epidemic as an unexpected large increase in the prevalence of a disorder. Given that definition, I think it is fair for him to use that term. I would call it a large increase, and our response, I believe, has been appropriate; that is, that we are mobilizing and we are assembling the structure, and putting it in place, that will provide resources for investigators to undertake large-scale studies that would not previously have been possible that are necessary to address a disorder that is occurring this commonly. That is our goal, and that is what our actions have been: to establish centers where young investigators who are interested in autism can be trained to go on and develop the science that is going to be necessary to have rational treatments for this disorder.

There is only so much we can do in a short period of time. Science is an endeavor that takes a lot of training and a certain amount of ramping-up to be able to use funding in an appropriate and very high-quality way. So we are hoping that we are putting in place the infrastructure that will allow that to happen.

Mr. SHAYS. Thank you. That is a very helpful answer.

Dr. Boyle, how would you respond to that question?

Dr. BOYLE. Well, I guess, rather than sort of fooling with the semantics of it, I feel, based on the work that we have done, the work that many other people have done, that the prevalence of autism is clearly much higher than what we previously thought, and that we need to have a concerted response to that issue.

I think at CDC we have strived over the last 5 years to do that, both in terms of trying to understand the magnitude of the problem, who's affected, and then by actually setting up sort of the research, epidemiologic capacity, to begin to address why this is happening.

It is clearly hard to look retrospectively and say, what was the rate 30 years ago, what was the rate 15 years ago. We don't have that data assembled. But I think it really shows us that in this country we need to understand that developmental disabilities, including autism, are extremely important conditions, and conditions that we all must take seriously.

Mr. SHAYS. Let me understand. It is my understanding that CDC is going to actually be reducing its spending next year on autism. Is this accurate, and if so, why would that be happening?

Dr. BOYLE. Well, actually, we were appropriated $9.7 million for autism in 2002. We also included additional funding for autism-related activities from the Vaccine Safety Program. I can actually let Melinda talk. We are still going to be expending the $9.7 million for autism that is specifically appropriated by Congress for those activities.

Mr. SHAYS. Let me just say something, just so I can put this on the record. I don't fault administrators when we in Congress don't appropriate the money, but where administrators become responsible is when they see a need and they can fill a need, they don't request the money, and then we in Congress don't respond.

I am getting the sense that in the last years this has been mostly generated by Congress kind of pushing NIH and others to treat this as a more important effort. I may be wrong, and I am happy to be corrected.

But, I'm sorry, you wanted to make your response?

Ms. WHARTON. Well, I was going to elaborate on what Dr. Boyle just said——

Mr. SHAYS. Sure.

Ms. WHARTON [continuing]. About the small reduction that you see in the projected CDC numbers for fiscal year 2003. As Dr. Boyle said, there has been a certain amount of money appropriated for autism activities, and that has been supplemented by vaccine safety appropriations. There have been a number of studies launched in response to different issues that have come up related to autism that have been initiated in the last couple of years. Some of those studies, the final funding cycle is in fiscal year 2002. So that accounts for the apparent reduction. In the fiscal year 2003 spending we have only reported to you what we currently anticipate spending based on the President's budget, but, of course, if additional issues arise that require additional studies, those might very well be the studies we would end up doing in fiscal year 2003, in response to new concerns or problems that arise.

Mr. SHAYS. When a President submits a budget, and I don't pretend to be a big spender, and I voted against spending, so I am not suggesting where blame lies here, but what I am interested in knowing, though, is if the President and the Budget Director are not suggesting enough funds for either of your agencies as it relates to this effort, have you gone on record as saying you need more money, not just with Congress? Let me start with the Budget Director, or are you basically just accepting whatever has been allocated?

Dr. BOYLE. This is really not done at my level. I clearly feel like this is an important issue, but it is really done at levels above me.

Mr. SHAYS. OK, Dr. Foote.

Dr. FOOTE. Well, the same is true for me, but, once again, to point out the way NIH does business, we have to have scientists who have the skills and the motivation to propose to us, even if we publicize an RFA, the kind of science that is necessary to address the issues. So we need to cultivate fields and we need to develop the competence and the expertise and the people and the resources to make the research possible. More often, that is a matter of sustained investment over a period of at least a few years to get fields really ready to take advantage of opportunities. So, yes, we have consistently, I think, advocated for that approach to biomedical research.

Mr. SHAYS. I used to chair the Human Resources Subcommittee of Government Reform and for 4 years had oversight of NIH and CDC, and so on, and FDA as well, and HHS. I am very familiar with the point you are mentioning. I think it is important to put on the record.

But would it be fair to say that you have a pretty good comfort level that if the field was hearing your testimony, that we wouldn't be flooded with people who say, "I've come in with proposals and I've been told there isn't the money"? Are you pretty comfortable in suggesting to this committee that there aren't a lot of people out there looking to do research in this area, and that you have to cultivate this group? Is this kind of what you are suggesting?

Dr. FOOTE. I think if there is appropriate training offered and if the structure that we are establishing and that other institutes at NIH have long supported, such as NICHD and NIDCD with their CPEA Program, the field expands because this is an interesting problem. This is a problem that scientists are motivated to get into and to try to help. There will be growth. As you know, once the seed is there, then sometimes growth can be quite rapid. So I think that is the scenario we are looking at, that in a few years, over the next few years, there will be investigators coming in with applications, and so on, and we will need to plan for some sustained growth in this area, so that people don't get disappointed. So that is the scenario we will be trying to plan for, sustained growth.

Mr. SHAYS. In our public life, just in our private life, we may come in contact with families and friends who have children that have different challenges, and autism being one of them, but in our public life, we're obviously exposed to more families. I find myself thinking, what if I was the parent? I would find myself somewhat frustrated with traditional medicine, given that it sometimes does seem to prod, traditional research. I would be very fearful that there weren't things that I was doing to my child, or had done, that may have contributed; in other words, if they were allergic to certain things, and so on.

So I have tremendous empathy as to why people don't want to wait too long, because wouldn't it be amazing to think that, when we discover something 5 or 10 years from now, we will learn that there were things we were doing for our kids, thinking we were helping them, when we were actually hurting them, and there were things that we could have done at a younger age that would have made them well, but at an older age may not have the same impact. I know you all have to have that sense as well.

I want to ask a few questions that the staff has prepared. So I will be reading a few of these, but I would like to put them on the record, and I would like the synergy of both of you responding and making comment.

But, Dr. Foote, this is to you. It relates to Dr. Ruth Kirchstein of NIH. I guess she is the Deputy Director, is that correct?

Dr. FOOTE. She is currently the Acting Director of NIH.

Mr. SHAYS. She published research she conducted in the 1960's on thermara——

Dr. FOOTE. Thimerosal.

Mr. SHAYS [continuing]. Thimerosal, yes.

Dr. FOOTE. Yes.

Mr. SHAYS. Our staff has been seeking to speak to her about this research and what other research she conducted relative to this. I am interested if you or anyone else at NIH is looking at this issue, and whether she will be getting back in touch with our staff. We need some cooperation from her, frankly.

Dr. FOOTE. I can carry that message back.

[Applause.]

Mr. SHAYS. Let me just say something to our guests. In this hearing it is truly a hearing, and so I want to respect your interests, but it is important that we have decorum.

Dr. FOOTE. My understanding is that was an FDA research effort. So I think probably it is also appropriate to request of FDA whatever documentation they have.

Mr. SHAYS. Can we, given that you are before our committee, can we anticipate that you will certainly try to help us in this regard?

Dr. FOOTE. You can anticipate that we have heard what you have said, and that we will carry the message back, yes. Thank you, Mr. Chairman.

Mr. SHAYS. Isn't it going to be important to evaluate the real-world treatment approach in autism and not just one therapy at a time? Let me just repeat the whole question. And don't you think it would be important to find a practice-based research center that is providing care for individuals with autism, so that we can track cutting-edge treatments in real-world situations?

Dr. FOOTE. Well, the issue of treatment, obviously is a primary one for families faced with an affected individual. As we were just discussing, it may be some time before there is a treatment founded and based on the pathophysiology of the disorder and derived in some rational way that really has a silver bullet approach to this disorder. In the meantime, people, of course, need to be trying to help their children, and doing it in as timely a way as possible, and in a way that is guided as much as possible by reliable information.

So NIH has in place several research programs focused on treatment. The CPEA networks have strong treatment components utilizing treatments that families are making use of right now, aimed at evaluation of their effectiveness and, as has been mentioned many times, which subset of affected individuals that treatment might be most appropriate for.

When we issued the RFA for the new STAART centers, the one requirement, absolute requirement, we had was that each application had to include a treatment component, a treatment study, and for a center to be considered to be fundable it had to have at least one treatment study that got strong ratings from the Peer Review Committee. So it has been our intention all the way along that in this major new effort treatment would be an inherent and major part of the overall effort.

Then I might note, finally, that this past year the NIH Autism Coordinating Committee issued an RFA as the result of which we funded seven applications having to do with new approaches to treatment, and we have funded those seven grants to get them going. So we are trying to undertake an effort where we are developing basic science for long-term treatment, but we are also doing these very much more immediate efforts where people have to find treatments; they have to use treatments now. People look for evidence. They say, "I want to use the kind of treatment that has the best evidence supporting it," and they often find that they go and look and the evidence base is very fragmentary, anecdotal, highly variable. It is not clear to them what to do when faced with this entire array of possible treatments. So we have undertaken efforts to try to help to deal with that as well.

Mr. SHAYS. Thank you. I am going to have the staff ask these questions, and ask as many as you want. I am going to listen to them. I might jump in, but I think that we might cover this more quickly to do it that way, given that they are going to be a little more familiar with your responses as well.

Ms. CLAY. Dr. Foote, when can we expect the NIH intramural program to replicate Dr. Wakefield's research?

Dr. FOOTE. I'm sorry, there was a distraction. When can we expect the intramural research program? I'm sorry, is that what you said?

Ms. CLAY. Yes. When can we expect children to be able to be seen at the NIH Clinical Center who have autism and who also have gastrointestinal issues to be investigated in the same manner that Dr. Wakefield did?

Dr. FOOTE. I don't know the answer to that. I would be glad to find out the answer to that and furnish it to you.

Mr. SHAYS. That would be helpful. Thank you.

Ms. CLAY. Yes.

Isn't it going to be important for the program at the NIH Clinical Center to be expanded for autism?

Dr. FOOTE. It sounds to me like that is addressing basically the same issue of what is happening on the NIH campus in terms of the ability of people to access that facility and get advice and potentially care, or enter into clinical trials, through that particular facility. I am afraid I don't know the answer to that. I will have to find out, but we will try to provide an answer that encompasses both of those questions.

Ms. CLAY. Dr. Boyle, we have talked about the CDC's Vaccine Safety Data Link project today. You have been tracking for 10 years vaccine adverse events through several HMOs. The committee asked for the raw data a couple of years ago, and we were told we could not have it because the HMOs were threatening to pull out of the project. We have learned that at least one pharmaceutical company has had access to the data through one of the HMOs and that other individuals have tried to receive this data through Freedom of Information Act and been denied.

Why has the pharmaceutical industry been given preferential treatment?

Ms. WHARTON. The study in question was actually done by one of the participating HMOs and was not a Vaccine Safety Data Link project. These individual HMOs each have their own research organizations which make their own arrangements with outside entities, including universities, pharmaceutical companies, vaccine manufacturers, and others, to do research using their patient population.

The particular study you are referring to, which I believe was initially on the list of VSD studies actually shouldn't have been on that list because it wasn't a VSD study. It was a study engaged in by one of the individual organizations in corroboration with a manufacturer, which they do many studies in terms of post-licensure safety studies, for example, these individual organizations.

Ms. CLAY. So your position is that no pharmaceutical company has had access to the Vaccine Safety Data Link project tapes at all?

Ms. WHARTON. That is my understanding.

Mr. SHAYS. Could you verify that? In other words, would you check that out?

Ms. WHARTON. Yes, we can get back to you on that, but that is my understanding.

Mr. SHAYS. And would you, in getting back, confirm yes or no? In other words, if your answer is the same, don't not get back to us; say that you have confirmed your answers.

Ms. WHARTON. Yes, I will do that. Thank you.

Mr. SHAYS. Thank you very much.

Ms. CLAY. In reviewing the publications that were provided to us from the CDC from this project, it appeared that an equal or more number of these projects were not looking at vaccine safety issues, but were looking at ways to increase immunization rates. Is that an accurate assessment?

Ms. WHARTON. I'm sorry, I can't answer your specific question.

Ms. CLAY. We were given about 45 published studies. Fourteen of them were looking at potential adverse event correlations doing vaccines. Another 14 or more were specific studies looking at how to improve immunization rates. So, in other words, how we were going to have increased uptake of vaccine usage within the HMOs, not at all about vaccine safety.

Ms. WHARTON. Well, the Vaccine Safety Data Link is used by the participating investigators to answer a variety of questions, including disease incidence, other issues beyond those related to vaccine safety, but it is still done within the same constraints of the system; that is, maintaining confidentiality of the patient records.

Ms. CLAY. Well, given the need to find out the issues of vaccine safety and the lack of research looking at adverse events, and that the creation of this project was specifically to look at adverse events, wouldn't it be important to put our focus there first?

Ms. WHARTON. Well, I appreciate your comments, and I can assure you that the people who are directly involved with the VSD project share your concern that the primary focus of the project has to be vaccine safety. The other projects that have been done through the system have really been, in general, smaller projects that have not required use of substantial resources. This system was created for vaccine safety, and vaccine safety continues to be its primary focus.

Ms. CLAY. And who at the CDC makes the decision of what projects can and cannot be conducted with the access to this data?

Ms. WHARTON. It actually is not CDC's decision. It is a collaborative project involving a number of health maintenance organizations, which, as I noted earlier, have their own research structures and their own principal investigators. This group collaboratively reviews protocols and makes decisions about what are appropriate uses of VSD resources.

Ms. CLAY. And as we move forward in having protocol established for outside experts to have access to this data, can we be assured that the data will be available fairly, and that there will be no reduction of access to the projects that they are requesting the data for?

Ms. WHARTON. Well, clearly, it is our intent to make the dataset available for re-analysis. A protocol will need to be developed and will need to be approved by the institutional review boards of the participating health maintenance organizations, but, yes, the dataset will be made available, the appropriate dataset will be made available for the re-analysis.

Ms. CLAY. Can we be assured then that if a researcher wants to conduct an independent analysis of Dr. Verstraeten's study, that can be done without bias?

Ms. WHARTON. You have asked a difficult question, and I may not be giving you quite the answer you are anticipating. Actually, I think there are some real issues with Dr. Verstraeten's study, and the epidemiological term for that is "bias." But, yes, what needs to be done is a protocol developed that will specify what data are needed for analysis, and those data will be provided in this confidential, in this secure setting of the Research Data Center at the National Center for Health Statistics using the existing model, following IRB approval.

Mr. SHAYS. Does the gentlelady, Ms. Watson, have questions that she would like to ask? We are having staff just pursue some questions, but if you have some questions or comments, I would love to recognize you.

Ms. WATSON. Let me just first thank the committee for holding this hearing. Since I am so late, I am wondering if there was a connection made between the fumes and the toxicity from mercury in the amalgams and autism. All right, we had kind of reached and bridged a gap. We thought there was some kind of connection.

Mr. SHAYS. If you would like to just ask a question or two about that, we would be happy to have you do that.

Ms. WATSON. Yes. Let me ask those from CDC, I'm carrying a piece of legislation that will prohibit the use of mercury in dental fillings. Fifty percent of that silver that they call silver is really mercury. The bill will outlaw eventually the use of it at all, but we want people very well informed when they go in to have fillings.

Can someone comment on whether there has been a connection made between mercury fillings and autism? Does that ring a bell with anyone?

Dr. BOYLE. I'm Dr. Boyle from CDC.

Ms. WATSON. Yes.

Dr. BOYLE. As far as I know, there has been no study that specifically addressed that issue in terms of dental fillings and autism.

Ms. WATSON. Yes.

Dr. BOYLE. No, there has not been a connection, but also there has not been specific studies.

Ms. WATSON. In my literature that we have collected around the bill, there has been some reference to not only autism, but serious conditions of brain deterioration suspected coming from that toxic substance that is emanating from the fillings. So I would like to let you know that my door and mail is open. If there is anything that you find in the literature that you could share with our office, it would certainly help us.

My staff is just handing me a note that is saying in some of the vaccines thimerosal contains mercury, and it is a kind of preservative, and it goes into the filling. So what we are looking for is any research, evidence, that would indicate a connection. Thank you.

Mr. SHAYS. Does the gentlelady from California have any other questions she would like to make?

Ms. WATSON. No, Mr. Chairman.

Mr. SHAYS. I am going to have the staff continue to ask questions. If you are still here and want to jump in, you could do that.

Ms. WATSON. Let me just ask one more question.

Mr. SHAYS. Sure. No, you have the floor.

Ms. WATSON. In your research, is it true that autism continues throughout a lifetime or can autism come to some point where the person comes back to very normal growth? Can someone comment on that?

Dr. FOOTE. Well, I think the observations are that it is a lifetime disorder with sometimes quite striking remission in certain symptom domains. The communication disorder, the communication problems, for example, can improve substantially. People have striking luck with certain kinds of treatments for parts of the disorder in certain children. But these tend to be sporadic, partial alleviation of the disorder rather than a sustained and total remission.

Ms. WATSON. Can the disorder be affected, say, for the good through a change in nutrition? Is there any evidence?

Dr. FOOTE. There have been reports—we were just talking a little bit earlier about the fact that the number of appropriately blinded, placebo-controlled studies in autism are several, literally several studies in the entire literature that have been very well done. Nutritional changes haven't been one of the domains in which there have been really careful studies.

So there are examples of alleviation of symptoms with dietary changes or nutritional supplements, but those tend to be anecdotal; that is, stories about a few to several people rather than carefully controlled clinical trials.

Ms. WATSON. Are autism patients treated individually? The condition can change for the better, but it still stays with them for the rest of their life? So my question is, can they be treated individually or is there a protocol?

Dr. FOOTE. Well, because we do not have broadly effective, standardized, rigorously demonstrated treatments, and people are confronted with serious difficulties in day-to-day life with an autistic child, people search for treatments. So, given that the typical story is that a given child will be exposed to several different treatment regimes over a period of time, the most broadly used treatments tend to be behavioral treatments rather than drug or other kinds of treatments. There are certain behavioral treatments, educational treatments, that with sustained large investments of time and effort can show substantial improvement in a large fraction of children. I think that is a fair statement.

Ms. WATSON. Institutionalization is one way to deal with this disorder. What percentage of those identified during their school years go into institutions, or do you have that information?

Dr. FOOTE. I don't have that information.

Ms. WATSON. Anyone?

Dr. BOYLE. From our work in Atlanta and Brick, there were no children who were currently institutionalized.

Ms. WATSON. There are no children in Atlanta or no children in your studies in the children that you know of?

Dr. BOYLE. In our studies of trying to establish the prevalence of autism, there are no children who were institutionalized. However, the whole issue of institutionalization in children, I mean there is clearly very few children who are currently institutionalized.

Ms. WATSON. Throughout the country?

Dr. BOYLE. Again, this is just in Atlanta and New Jersey.

Ms. WATSON. Just in Atlanta. So you don't have any information countrywise? That is something I would like to know. I know in California they do institutionalize. I know in Massachusetts they institutionalize. I am just wondering how prevalent it is across the country. Thank you.

Mr. SHAYS. Dr. Foote and Dr. Boyle, let me just say it is our intention to let you get out pretty soon. You haven't had a break or anything. Do you have 20 more minutes in you? Are you OK?

I am going to do something that may seem a little unusual, and I may have to just cut it off if it is not a good idea. But, Dr. Foote and Dr. Boyle, if you can trust me in terms of my ability to control a meeting, it is not lost on me that we have a lot of people in the audience who have a keen direct interest. There may be a question or two that none of us on the panel here have asked that we should have. I am going to ask if there is someone in the audience who may have a question that says we should have addressed this. I will allow you to stand up and tell the committee, and then we may choose, our committee may choose to ask that question.

My motivation is that it would be a shame to have people leave without you having the opportunity to respond and maybe clear something up. Both of you have such a nice, friendly smile. I figured I could get away with it. So we are going to try it out, but I have the counsel—excuse me, the minority counsel would like to ask you a few questions, the majority professional staff would just like to ask a few more, and then I am going to just throw it out to the audience, pick two or three of you and ask you to stand and tell me if there is a question you think we should have asked, loud enough so I can repeat it to our witnesses.

There you go. So I will recognize the minority counsel. Yes? Mrs. Morella, I had asked if there was any question, and I had been told you didn't have any. Would you like the floor?

Mrs. MORELLA. I would love it.

Mr. SHAYS. You have the floor as long as you would like.

Mrs. MORELLA. Particularly because I represent the National Institutes of Health, and, Dr. Foote, I am glad you are here, and I work very closely with CDC, and I am glad you are here, Dr. Boyle, too.

I was here for the first panel and heard the kinds of questions or the points that they brought out. I think one of the notes that I had jotted down was they felt there was a need to develop a national policy, that we needed more collaboration, that we needed to match the child to the method.

We pointed out the fact that there are just so many questions that are still unanswered. Funding was stressed by I think every member of that first panel. I am not sure—if you would kind of comment on whether you see, what do you see is really necessary? Is it the need for further collaboration? Will funding alone do it? How do we get some of these questions answered, particularly also with regard to vaccines and what their connection is to autism? If any of you would like to comment on that just general area? Dr. Boyle.

Dr. BOYLE. I will start. I took some notes, too, during the last panel. I would applaud the issue of collaboration. I think we have made a good start across not just NIH and CDC, but all the agencies involved. The Department of Education, the Health Services and Resources Administration, all of these agencies need to work together to address this issue.

Mrs. MORELLA. Should we do something about that? I mean, is there direction we should be offering?

Dr. BOYLE. I think the direction from Congress from the Child Health Act clearly directed collaborations. It directed, I think, to CDC and NIH, but other partners have clearly been pulled into that. I think that we need to continue to make that happen, as well as work with all of the parent groups that are seated behind us here.

I applaud the effort of hearing from the parents at the end of the committee hearing today. So I would definitely second that notion.

The other thing I heard about was, though, the issue of training.

Mrs. MORELLA. Yes.

Dr. BOYLE. And this is training across the board. I think a lot has happened in the last 5 years in terms of both epidemiology researchers, diagnosticians, treatment issues. I think that we have made clear progress, but I do think this is an area that we need to put concerted energies into.

There is a lot of interest in autism and other neurodevelopmental disorders, and we want to continue to have that momentum happening it and growth in positive ways.

Mrs. MORELLA. Dr. Foote, I would love to give you an opportunity to respond to any of those facets.

Dr. FOOTE. Well, the Children's Health Act called for the establishment of an Interagency Autism Coordinating Committee. We now have that up and running. There is, of course, always a big distance between sitting down in the same room and talking and converting that into something that resembles a national policy or even a coherent picture of what it is that is being done, which, of course, helps you identify what isn't being done.

But I think at our first meeting, and I think on the agenda for our second meeting of that committee, those are exactly the jobs that we are taking on. I think we have the appropriate representation on the committee to be able to do that in a realistic way. So I think if there is going to be a national agenda about autism, I think that there is a kernel for starting that with the Interagency Autism Coordinating Committee.

Mrs. MORELLA. Maybe this committee hearing will help to spur that on.

Thank you, Mr. Chairman. I am pleased also to note your new concept of involving the audience, involving the parents.

Mr. SHAYS. Well, we have done it before and it has worked, but it does take cooperation.

Mrs. MORELLA. Right.

Mr. SHAYS. We will give it a try in a second. Excuse me for not calling on you; I apologize. I think it was the nervousness of thinking how we were going to do the latter. [Laughter.]

I recognize minority counsel.

Ms. DESPRES. Thank you. I have just a couple of questions regarding that request for the Vaccine Safety Data Link data. I was wondering if you could explain to us why the privacy concerns are so important. I am particularly interested in what could happen to the VSD if the participating HMOs didn't believe that there was adequate control over patient confidentiality.

Ms. WHARTON. Well, in fact, I think just the fact that this discussion has been ongoing for so long has convinced all of them that there is no longer assurance that the data can be maintained in a private way at CDC. The individual participating organizations are no longer sending master datasets to CDC. I think that unless these issues can be resolved, the project is likely to no longer be possible to continue.

What we have tried to do is develop a new way of doing studies where, in fact, the data won't reside at CDC, but the analyses will be done in a distributed way among the participating organizations. This is something which is theoretically possible to do, but operationally would clearly require much more in the way of data management and statistical support of the individual sites, as well as at CDC. So I think, in effect, it will reduce the amount of work that will be possible for us to accomplish within the VSD with existing resources.

Ms. DESPRES. Can you explain to us, if the VSD is not able to continue, what would be the implications for vaccine safety research in the future? I am also curious about the implications of the fact that the data currently is not at CDC. What present implications on vaccine safety research has that had and what implications could it have in the future.

Ms. WHARTON. Well, at the moment we, as I understand it, have not yet received any of the year 2000 data because none of the organizations are currently willing to send it to us. So we are not currently able to perform any studies easily in terms of screening analysis that requires access to the year 2000 data. Now, again, the data do reside at the individual sites and can be accessed in this distributed way, but it is far more laborious.

Should the project cease to exist, I think it would dramatically change—it would be a great loss for us. The VSD has provided a mechanism through which vaccine safety concerns could be rapidly addressed, and often reassurance provided in a very prompt way when something comes up. Now many issues are complex and do require more detailed investigation beyond what can get from analyzing the automated data tape, and do require chart review, and so forth. Those studies are more complicated and take longer to perform, but the VSD has really been one of the bedrocks of our vaccine safety system. I think its loss would be a great one.

Dr. BOYLE. Can I add a comment to that as well? I think that this actually has had a ripple effect with the HMOs. We are dealing with other issues where we would like to have a rapid response and work with the HMOs because they are a wealth of information and data, and they are reluctant to participate because of these privacy issues.

Ms. DESPRES. So without having VSD data now and the possibility that you won't have it at all in the future, would that mean that it could take longer to detect vaccine adverse effects?

Ms. WHARTON. It clearly would take longer. It would clearly be more laborious. It clearly would be more resource intensive, and we would be unable to accomplish as much.

Ms. DESPRES. I don't have any more questions. Thank you.

Mr. SHAYS. I thank you very much. It is important to get on the record. I appreciate it.

I recognize the majority professional staff.

Ms. CLAY. Aren't some of the privacy concerns as a result of the HIPAA regulations that are about to be implemented?

Ms. WHARTON. Some of the privacy concerns do overlap with HIPAA issues. There are additional State requirements in some of the States in which these organizations persist. But it is a general issue that we have to assure the confidentiality of these data.

Ms. CLAY. And is their not providing the tapes to you a violation of the contract that you have with the association that oversees these HMOs?

Ms. WHARTON. We are in the process of trying to develop a new procurement mechanism that will allow development of this distributed model.

Ms. CLAY. One of the correlations that we have looked at between the issue of mercury in medicine and exposure for our children is the same process that we went through in the 20th century looking at lead in paint and its effect on children. How does this issue correlate, the CDC and the NIH response correlate for mercury as it did to lead in the paint 50 years ago?

Dr. BOYLE. Well, I will start first. One of the things that we are hoping to be able to do with our State-based program is to be able to monitor, and we call it, from an ecological standpoint. The implications you have had were in terms of looking at lead. But we are hoping to be able to look over time at the prevalence of autism based on our State-based monitoring program and how that prevalence may have been impacted based on the removal of thimerosal from vaccines.

Dr. FOOTE. I think the NIH response to the thimerosal issues has been to undertake a series of research projects looking at metabolism, and distribution of ethyl-mercury in the body, rates of clearance, and potential toxic effects. There are several such research efforts now underway, some of which, as we discussed earlier, and in collaboration with CDC. So I think this is a serious and appropriate response to those issues.

Ms. CLAY. And, Dr. Foote, if a parent, when they have a newly diagnosed child, goes to the NIH Web site and looks for information on therapies for the child, will they find adequate information?

Dr. FOOTE. Well, we have a joint linkage with the National Library of Medicine in which there are large amounts of data available. The real problem is one of the underlying science and the underlying science not being adequately developed. Anybody would be daunted right now in attempting to sift through that information. I don't think it is as much a matter of organizing the information as it is of literally developing the information, and that is the effort that we have underway. So, yes, we have taken seriously the task of having an interface with the public that makes information accessible to them, but our real job and the real effort that is going to solve this problem is to have better information available.

Mr. SHAYS. Now let me state what I would like to do. I would like to let our witnesses leave soon. I would like to just say that this is a hearing of the House of Representatives, of Congress, so the decorum needs to be done well.

I am going to first ask how many people would like to ask the question. I am going to invite five people to take each of those five seats. I am going to invite you, Ma'am, in the front row to come up to that seat up there, yes. I am going to invite you in the very back to come up, the very back there. I am going to invite you, sir, to come up. I am going to invite you, Ma'am, in the middle, and I am going to invite you in the very back there.

I am going to have you each take a seat. What I am going to invite each of you to do, the committee is going to invite each of you, you are just going to go down and you are going to identify your name, as you ask the question, where you live. If you have a loved one who is impacted, we are happy to have you share the name of your child, but this is primarily for an opportunity to ask a question. We will just see how it goes. OK?

You all are nice—thank you—to let us do this.

Just turn the mic on, start at the very end, and ask your question.

Ms. MINTZ. Hi. My name is Sandy Mintz. I am from Anchorage, AK. I am lucky enough not to have a child who has been injured by a vaccine.

My question is, is NIH ever planning on doing a study using the only proper control group, that is, never vaccinated children?

Dr. FOOTE. I am not aware of—but note carefully what I said, that I am not aware of—a proposed study to use a suitably constructed group of never vaccinated children. Now CDC would be more likely perhaps to be aware of such an opportunity.

Dr. BOYLE. The study that I mentioned earlier that we are doing in collaboration with Denmark compares children who received the MMR vaccine versus children who did not receive MMR.

Ms. MINTZ. But I am saying never vaccinated with any vaccine. That assumes that other vaccines don't cause autism, which is what needs to be studied, not assumed.

Mr. SHAYS. Let me just say that if you would turn off your mic, I am happy to have you do the followup, if you would respond to it.

Ms. MINTZ. I'm sorry.

Mr. SHAYS. No, you don't need to apologize. And we will go to the next. Do you have any other comment based on that? The point that is being made, any vaccination. Could we just suggest that you take this under advisement?

Ms. WHARTON. The difficulty with doing such a study in the United States, of course, is that a very small portion of children have never received any vaccines, and these children probably differ in other ways from vaccinated children. So performing such a study would, in fact, be quite difficult.

The Denmark study was a study that, in fact, could not have been done in the United States, although, of course, these children did potentially receive some other vaccines, but simply hadn't received MMR.

Mr. SHAYS. I will invite anyone who is here to speak to staff or me afterwards if they want to augment a comment.

Let's go to the second person. I am sorry, I don't know your name. So I can't call you by name. So you are going to be a number to me.

Ms. STEWART. OK.

Mr. SHAYS. You are No. 2.

Ms. STEWART. OK. My name is Dr. Linda Stewart. I am from New York. I am coming from Switzerland. I have been working in Switzerland for 30 years in the political and internal affairs international arena. I am also a mother of a son, my No. 2 son, who has been recently diagnosed with autism spectrum disorder.

Mr. SHAYS. How old is your son now?

Ms. STEWART. He is 8.

Mr. SHAYS. OK.

Ms. STEWART. We returned to the United States, as he was born and vaccinated in Florida. We had been to four or five neurologists in Europe, the highest doctors we could find in France, Switzerland, Italy, and we came to the United States to find out if we could find any help for the boy since he was born and vaccinated here.

All the tests, MRIs——

Mr. SHAYS. Let me ask you, can you do your question, if you could, yes?

Ms. STEWART. Yes. All our tests showed normal, and we were able to find a program by residents from NASA that showed the child was full of mercury. My question to you, respectfully, as scientists and researchers, what results, with all the millions that I hear you mention back and forth today, what have been your results in a pragmatic and functional level for the millions of research that you have received in biological autism?

Dr. FOOTE. The types of studies that happened and are underway are studies about the levels of mercury that result from vaccination and are about the timing of the onset of autism symptoms in regressive and/or non-regressive autism and how those may be or may not be systematically related to the time of vaccination.

Some of those data are in; some of those studies are currently being conducted, and some of those studies are still being organized. The data are not yet in. But the money is on the table. The studies have been funded and they are underway.

Ms. STEWART. Thank you.

Mr. SHAYS. No. 3.

Ms. WEDEWER. Hi. My name is L.D. Wedewer. I am the U.S. Autism Ambassador, and I have more titles than my arms, so I will leave it at that.

But I have a two-part question actually. My daughter received a hepatitis B shot at 2 days old, which I truly feel was too young, but I was never given any information on the cause and effect, what could happen to her. Do you feel that there is a need to ensure that parents have the knowledge of what the mercury could do to the individual, and how would we assure that?

Ms. WHARTON. Well, clearly, we do try to inform parents of the known risks and benefits of vaccination through vaccine information statements, which are required by the National Vaccine Injury Compensation Act passed by Congress some time ago.

The mercury is no longer contained in any of the hepatitis B vaccines administered to infants or thimerosal is not, and thimerosal—the vaccines now being routinely administered to children, in fact, none of them contain thimerosal at this point.

There are not data to—there are no established harms associated with this. I know this is a subject of great concern, and a number of studies are underway, but we do not have data that support known hazards associated with thimerosal contained in vaccines at this point.

Ms. WEDEWER. OK, and my second part to the question is I have, as the U.S. Ambassador, I have been receiving over the last year numerous information and different amounts of proof on the thimerosal connection, Ma'am, as my daughter is one of them. I had found a recent CDC report that had never been released that had birth to 6 months, and yet the release that you released to the public and congressional hearings omitted birth to 6 months. Is there a reason why the original report and the second report do not match?

Ms. WHARTON. Well, this is an issue that was addressed earlier. I believe the study you are referring to is Dr. Thomas Verstraeten's analysis of the VSD screening data.

Ms. WEDEWER. I actually have it here today, if you would like to have it in front of you, so you know——

Mr. SHAYS. No, but she is on target, right? She got the study.

Ms. WEDEWER. OK, go ahead.

Mr. SHAYS. Yes.

Ms. WHARTON. And as I mentioned earlier, the initial studies focused on a limited followup period. Since that time, there has been more extensive followup which should actually enhance the finding of children whose subsequent developmental abnormalities were diagnosed later in life. So more extensive followup should help us do a better study.

Ms. WEDEWER. OK, my final, this is the final part to it, and I promise I will let Mr. Horowitz go on. My last concern—and, remember, I receive e-mails from many, many parents; I was inducted by more than 245,000 people, so I——

Mr. SHAYS. Ask your question. Why don't you ask it.

Ms. WEDEWER. I have U.S. knowledge. May I ask, why, then, if you are so worried about releasing the statistics from the parents to a congressional hearing, as I do work with Democrats, etc., in Iowa, do you really think—as a parent of a child with autism, I don't think that I would have a problem with you releasing the information for someone else to look at. Do you really think that other parents would have problem with that, when everybody they see——

Mr. SHAYS. OK, you have asked your question. Now I am going to have you move the mic, so I know you are not going to have a fourth followup.

Ms. WEDEWER. OK. [Laughter.]

Mr. SHAYS. OK.

Ms. WHARTON. Well, it is not just parents of children who have neurodevelopmental abnormalities. It is all the patients participating in these health maintenance organizations, which is a measurable proportion of the U.S. population, have data on every medical encounter and every diagnosis they have received. I think these are data which have to be maintained confidentially. We have no choice about that.

Mr. SHAYS. Thank you. We have two more to go, and you all have been wonderful. Yes, sir, you are No. 4. Turn the mic on, if you would.

Mr. HOROWITZ. Thank you. My name is Dr. Len Horowitz. I am here representing an organization nationwide called Vaccination Liberation, as well as I am an Honorary Autism Ambassador, and I appreciate this opportunity.

My question is not simply for the good representatives here, but also for all of us to consider. We have currently in the last several years particularly become very aware of the tobacco industry and its infusion into what amounts to cancer sticks, a variety of ingredients that the industry itself knew was totally toxic. The evidence before this committee, I understand, including the Verstraeten report, indicates clearly the Centers for Disease Control and other industry officials knew well in advance that mercury, as well as potentially aluminum, formaldehyde, formalin derivatives, as well as foreign species DNA, RNA, proteins, cause a horrific number of injuries.

The question that I have is, how, as we begin to spend millions of dollars and give to these same organizations who have this knowledge, how can we assure that putting virtually the fox in charge of the hen house do we expect this autism pandemic or epidemic here in the United States to stop without a full housecleaning within the NIH, CDC, NAID, NIMH, and FDA, freeing this bureaucracy from special pharmaceutical industry biases and influences, especially since the lives of our children, our Nation's future is at great and grave risk?

Mr. SHAYS. OK, let me say, you are not going to have a followup on that one because that was such a long question, and it did have a sense of bias as well as a statement, but it is an important question to put on the record.

I don't know if you all want to address it. It was thrown out to all of us. Do you want to just make any response? I mean, Dr. Foote, can you—let me try to narrow it down a little bit.

Given that we did know that there are a lot of things that we have allowed to happen where we knew they shouldn't, how do we sort that out? In other words, in Congress, in the private sector as well, I mean we could say with hindsight we know it shouldn't have happened. We can say, well, some people in a company may have known, but maybe not everyone. Just he deserves some type of response.

Ms. WHARTON. Well, I would call into question the initial statement that we know that all these additives are in vaccines and we know that they cause harm.

Mr. SHAYS. Right.

Ms. WHARTON. In fact, that is not known. The Institute of Medicine has reviewed the data regarding IOM and autism and has found that the evidence favors rejection of a connection between MMR vaccine and autism. As far as the thimerosal issue is concerned, the evidence is too incomplete and fragmentary to make any decisions about causation.

Of course, many substances are known to be dangerous when administered in high concentrations, but the additives that are included in vaccines are present in trace amounts, and even when multiple vaccines are given, these are still very small amounts of products. It is not established even that thimerosal is associated with any harm as a vaccine additive.

That said, we have committed a large amount of staff time and funding to try to further elaborate these issues and have designed a whole series of studies that have been described in our written testimony that we believe will help address these issues and are responsive to the specific research recommendations made to us by the Institute of Medicine.

Mr. SHAYS. Thank you. I am going to respond and say that some of our most dedicated employees are in the very institutions you have mentioned. So I would dispute that we need a cleaning of the house, but I do think——

Mr. HOROWITZ. Just in terms of those biases by special interests, currently, the waivers bother me, the fact that we have CDC officials and ASIP officials in the vaccine——

Mr. SHAYS. You know what we are going to do——

Mr. HOROWITZ [continuing]. That get these waivers——

Mr. SHAYS [continuing]. We are going to allow you to have dialog directly with the staff about this afterwards, and the staff will stay.

Let me just go to No. 5, and then you all have been very trustworthy, and I thank you, and I know it is tempting to jump in, but you won't be given an opportunity. We are going to five, and then you all are going to get home.

Ms. BIGELOW. Hi. I am Rita Bigelow. I have an 11-year-old boy with autism. I just want to say thank you to the Congressmen and women who are here helping us with this cause, and also to the people from the NIH. Thank you for listening to us, answering our questions.

Mr. SHAYS. And CDC.

Ms. BIGELOW. And CDC. Sorry.

Mr. SHAYS. Yes.

Ms. BIGELOW. I am with the Autism Coalition and with other groups. I see many of my friends who are here, too. So thanks to all of them for making the trip down.

I have a question that is a little bit taking a different tack, but I worked with several researchers in autism, tried to raise money for them, and worked with them. It seems that most scientists believe that autism is caused by a combination of genetic and environmental triggers.

My specific question, and I don't have a part B, but, what types of steps has the NIH taken to promote genetic studies? You know, the genes may perhaps interact with environmental triggers, with psycho-pharmacologic agents, things like that.

Dr. FOOTE. So the CPEA network that has been funded for the past several years by NICHD and NIDCD has a coordinated genetics program, their Centers of Excellence in Neurobiologic and Genetics of Autism, where they have multiple sites at which they collect genetic data from subjects. The advantage of having multiple sites being that you can collect from them a much larger cohort than you could ever do having individual investigators operating just within their own spheres. So it provides power to genetic analyses that couldn't otherwise be obtained.

In the new STAART Centers Program, we will be doing the same kind of thing, where there will be standardized diagnostic protocols across all of the sites, standardized instruments, so that then you can collect genetic data from a large number of subjects distributed at various sites and have the numerical power to do genetic analyses that wouldn't otherwise be possible.

We have at NIMH a genetics repository where we collect large amounts of genetic data and make it available to any responsible investigator who applies to us to receive genetic materials from rigorously diagnosed subjects about whom we have large amounts of information.

So this is the future. This is what we are actively implementing. We recently just gave a multimillion dollar grant to the AGRE data base, which you may have heard of, which has originated from advocacy groups, and really the grassroots, generating genetic samples. So now we feel like we are in the position where we can have a very large data base of genetic information combined with very detailed behavioral and clinical information from subjects, so that we can do powerful genetic analyses.

Then just one final note, and then I will be quiet, because you hit one of my buttons here, obviously. The other issue is that some of these questions that come up, "Why did my child respond so dramatically to a particular vaccine when all the other kids on the block didn't respond the same way?" Well, the genetics may well be a clue to that. The way we are going to get the answer eventually is through these combined genetics efforts where we have a large number of subjects, thorough clinical histories, standardized genetic information, freely available to a number of investigators who may well want to look at exactly this question. So that is where we are going. We are getting there.

Mr. SHAYS. Dr. Boyle.

Dr. BOYLE. I was just going to be very brief. In our centers' studies, these are epidemiologic studies that are done collaboratively, sort of what we call gene environment interaction. This is a very important issue, and it is clearly one that is the basis for the studies, and that is what we are addressing.

Mr. SHAYS. I thank all five of our——

Mrs. MORELLA. Mr. Chairman, may I just add something to that?

Mr. SHAYS. Sure.

Mrs. MORELLA. That is where you are going to need the passage of the Genetic Non-Discrimination in Employment and Health Act, which has about 260 co-sponsors here on the House side.

Mr. SHAYS. I hope I am on that bill. Good grief.

Mrs. MORELLA. I think you are, yes. [Laughter.]

Mr. SHAYS. Ms. Watson, do you have any last comments you would like to make?

Ms. WATSON. No, I don't except to thank the panel.

Mr. SHAYS. Yes. I am going to ask this question. I have one other question.

Mrs. Morella, any comments?

Mrs. MORELLA. No, Mr. Chairman.

Mr. SHAYS. I had a question that I was asked to give, and I think by the response to one that we are doing this. But the question was, do the CDC and NIH recommend that the removal of thimerosal from childhood vaccines—it appears that is the case, that we are removing them from childhood vaccines? Is that the case?

Ms. WHARTON. That recommendation was actually made in 1999.

Mr. SHAYS. Great.

Ms. WHARTON. And the vaccine manufacturers moved very quickly to reformulate and relicensed all the routinely administered childhood vaccines, so that they are now available only in thimerosal—they are now marketed only in thimerosal—in formulations that do not contain thimerosal as a preservative.

Mr. SHAYS. Got you. Let me ask you this now: Is there any question that you had prepared to answer that we never thought to ask that you want to answer? [Laughter.]

[No response.]

Mr. SHAYS. I think that our guests would recognize that you all have been very patient, and I think our witnesses would recognize that you all, those of us who are our guests at this hearing are dealing with some really tough issues. We want to be helpful to you and want you to stay in touch with our committee. Our committee record will be open until the 3rd, and you are invited to submit anything in writing to the committee that you would like to submit.

But I do thank all of you for participating here, and I thank No. 1, 2, 3, 4, and 5 for being here and your patience in not having the sixth or seventh followup.

This hearing is now adjourned. Thank you.

[Whereupon, at 5:10 p.m., the committee was adjourned, to reconvene at the call of the Chair.]

[The prepared statements of Hon. Thomas M. Davis, Hon. Wm. Lacy Clay, Hon. Christopher H. Smith, and additional information submitted for the hearing record follow:]

TOM DAVIS
11TH DISTRICT, VIRGINIA

COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON TELECOMMUNICATIONS AND
THE INTERNET

COMMITTEE ON GOVERNMENT REFORM
CHAIRMAN,
SUBCOMMITTEE ON TECHNOLOGY
AND PROCUREMENT POLICY
SUBCOMMITTEE ON THE DISTRICT OF COLUMBIA

Congress of the United States
House of Representatives
Washington, DC 20515–4611

306 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225–1492

DISTRICT OFFICES:

7018 EVERGREEN COURT
ANNANDALE, VA 22003
(703) 916–9610

730 ELDEN STREET, SECOND FLOOR
HERNDON, VA 20170
(703) 437–1726

13554 MINNIEVILLE ROAD
WOODBRIDGE, VA 22192
(703) 590–4599
www.house.gov/tomdavis

Statement of Representative Tom Davis regarding the House Government Reform Committee Hearing Entitled "The Autism Response – is the NIH and CDC Response Adequate."

As a member of the Congressional Autism Caucus, I am well aware of the extreme hardships placed upon those families with autistic children. This mysterious, life-long condition places severe strains not only on the immediate families, but also their surrounding communities due to their extensive and specialized educational and health care needs. This experience must be all the harder for those families whose children appear unaffected at birth, but slowly slip into the grasp of autism as they get older. The happiness and joy at the promise of a budding new life in these cases fades into confusion and anger as the child closes himself off from the world around him. While there are numerous treatments for autistic children, there is no definitive explanation as to the cause of the disorder, nor is there a cure. With the occurrence of autism on the rise, there is a dire need to expand our efforts to unlock the secrets of autism, and I greatly appreciate the continued efforts of Chairman Burton to pursue this objective.

Tom Davis

PRINTED ON RECYCLED PAPER

Statement of the Honorable William Lacy Clay
Before the
Government Reform Committee
April 18, 2002

"The Autism Epidemic – Is the NIH and CDC Response Adequate?"

Mr. Chairman, I would like to thank you for convening this important hearing regarding the autism crisis. I would also like to take this opportunity to thank the Autism Society of America, and it's President Lee Grossman, for helping to educate us all on the challenges that are associated with autism. Autism is a brain disorder that affects an estimated 500,000 to 1,500,000 people and is rising at an epidemic pace.

Over sixty years have passed since Autism was first identified as a medical brain disorder. The disorder is a lifelong condition that usually manifests itself by age three predominately in male children. The cause of the disorder is uncertain, although some medical professionals believe that it is based on genetic conditions. Unfortunately, the condition cannot be currently diagnosed through medical tests. Parents and pediatricians must first rule out other disorders before concluding autism as the apparent condition.

Mr. Chairman, I would like to commend the National Institutes of Health and the Center for Disease Control for their on-going research efforts. They have been working diligently to better understand the disorder, and are continuing to search for possible treatments to alleviate the condition, and improve the quality of life for those individuals that are affected. During this national autism awareness month, we would be wise to remember that while much has been done much more is needed. In closing, I would urge my colleagues to support the continued funding of autism research. Mr. Chairman, I ask unanimous consent to submit my statement into the record.

CHRISTOPHER H. SMITH
4TH DISTRICT, NEW JERSEY

CONSTITUENT SERVICE CENTERS:

☐ 1540 Kuser Road, Suite A9
Hamilton, NJ 08619-3828
(609) 585-7878
TTY (609) 585-3650

☐ 108 Lacey Road
Whiting, NJ 08759-1331
(732) 350-2300

WASHINGTON OFFICE:

☐ 2373 Rayburn House Office Building
Washington, DC 20515-3004
(202) 225-3765

Congreſs of the United States
House of Repreſentatives

COMMITTEES:

CHAIRMAN
VETERANS' AFFAIRS COMMITTEE
Subcommittee on Benefits

VICE CHAIRMAN
INTERNATIONAL RELATIONS
Subcommittee on International Operations and Human Rights
Subcommittee on East Asia and the Pacific

CO-CHAIRMAN
COMMISSION ON SECURITY AND COOPERATION IN EUROPE

STATEMENT OF REPRESENTATIVE CHRISTOPHER H. SMITH
April 18, 2002

Thank you Mr. Chairman. As one of the two co-chairmen – along with my good friend Congressman Mike Doyle of Pennsylvania – of the Coalition for Autism Research and Education (CARE), I appreciate this opportunity to talk briefly about this most important of public health issues, and our government's response to helping the victims and their families. The Congressional Autism Caucus, which we formed just one year ago, already has nearly 170 bipartisan members, and I expect support will continue to grow.

Let me extend my thanks to Chairman Burton for having this hearing and for all his years of dedication in keeping a national focus on autism and providing hope for all the children and adults living with autism and hope for their friends and families. I'd also like to add my commendation and admiration for the families living with autism and for the national autism organizations -- such as the Autism Society of America, Cure Autism Now, and the National Alliance for Autism Research -- without whose advocacy we would not be here and there would be no hope.

Finally, let me recognize the federal agencies represented at this hearing, the CDC and the NIH, for their activities - particularly in epidemiology and research - that, hopefully will lead us soon to some real solutions. With the implementation of the Children's Health Act of 2000, we have a much more solid infrastructure in place for launching an effective assault on autism, and these agencies should also be commended for their progress. But now our expectations for the future are high and we will be looking to the federal agencies for real results that have a tangible impact on prevention and on the lives of families already living with autism.

But the reality today is in stark contrast to our hope for the future. Not only are we not reducing the prevalence of autism, but its incidence appears to be growing significantly. We absolutely cannot allow the numbers of children diagnosed with autism to continue to climb. I want the witnesses here today to take back to their agencies the message that we all need to tear down whatever barriers are slowing progress.

Let me conclude with an example of a problem that has been a major impediment to progress. A federal education privacy policy known as FERPA - the Family Educational Rights and Policy Act - is hindering researchers working to collect information on new cases of autism and autism spectrum disorders. The privacy policy is intended to protect our school children, but

PRINTED ON RECYCLED PAPER

in this case it is keeping our researchers from gathering data that will help us learn more about autism. In my own state, personnel have told me they are ready to gather data but are forced to sit on their hands. If researchers do not have the opportunity to enter our schools and obtain the information needed to learn more about autism, the entire surveillance project that many of us worked so hard to move along could be hamstrung.

Myself, Rep. Doyle, and others – including autism advocates – have been working for months to try and resolve this issue. The CDC and Department of Education both agree that this is a problem that must be corrected, but they have not come up with an agreement to solve the problem. Months have elapsed and we are still no closer to gaining access to this vital information. While some of the information can be gathered through other avenues, the health community has been clear that the majority of the data will come from children enrolled in public schools. The patients and families involved become aware of such delays and become very frustrated.

The federal agencies involved need to expeditiously resolve the FERPA quandary, with legislation if necessary. Eliminating this barrier to data on affected children should open the door to significant progress in understanding aspects of autism, and we can continue to move forward.

April 11th, 2002

Dear Members of the Government Reform Committee:

My name is Donna Carver. I am an Ohio Representative for the World Wide Organization Unlocking Autism.
For more information on Autism please visit our Website www.unlockingautism.org

Today, I am writing to you **not** as a Representative of the organization, but as a parent of 3 children including a beautiful 7-year-old son diagnosed with Autism Spectrum Disorder.

I would like to Thank Chairman Burton and Congressman Waxman for co-sponsoring HR 3741.

I am writing to urge the remaining reform committee members to support HR 3741 known as the Burton/Waxman Bill.

Before my son Andrew's birth, I worked as a nurse. I firmly believed in the medical profession as well as the governmental agencies that are designed to protect and research infectious diseases and the childhood immunization policies.

I dutifully immunized my child using the recommended childhood vaccine protocol at the time of his birth.

This included the hepatitis B vaccine at birth and the MMR vaccine at 13 months. After the MMR we noticed regression of language and eye contact as well as other symptoms that, at the time didn't know, are related to the MMR vaccine as a vaccine injury. It severely affects his neurological system, immune and gastrointestinal systems. He "looks" like any other child but engages in behaviors that can harm himself and others. He does not understand danger. He requires constant supervision and suffers from a sleep disorder, which make it possible for him to live on only a few hours of sleep a night.

My family has gone from living the American dream to living the ultimate American nightmare. We suffer from the constant stress of having to be vigilant at every moment. Simple tasks like showering or a nap are now luxuries in our daily lives. Our marriage and our other children are strained due to the constant needs of our son.

Autism Spectrum disorder is typically not diagnosed until age 3 to 6. The current National Vaccine Injury Compensation Program (NVICP) requires that a claim be filed within 3 years of onset of injury.

(Compare that with the current laws governing auto accident injury.

If my son had been injured in an auto accident he would have until 2 years after his 18th birthday to file a claim for injury.)

Due to the misunderstanding of Autism Spectrum Disorders and especially regressive autism, many parents are unaware until years later, when appropriate tests are completed, that the MMR vaccine in fact damaged their child.

This excludes them from NVICP and denies them financial compensation for their child whose injury is a life long severe condition.

Most major health insurances exclude autism from their policies. Parents must pay for needed medical services out of pocket.

Educational programs that greatly benefit our children are almost impossible to obtain unless funded out of pocket. The NVICP may be the family's only way to adequately care for their child. **HR 3741 makes the needed changes that will benefit our families.**

Without this option, many children will become the states responsibility to care for. With the current nationwide epidemic of Autism Spectrum Disorders, we can no longer afford to NOT assist these children with habiltitative services that can make the difference between an adult tax payer or an adult that is institutionalized and supported by the state.

Please support families like mine. Please Support HR 3741.

I can be reached by phone at my home [redacted], by cell phone at [redacted] electronic mail at [redacted]
My mailing address is: [redacted]

Hundreds of thousands of Families across Ohio and the nation, including mine, are counting on you to Support HR 3741.

Respectfully,

Donna J. Carver

Donna J. Carver

Dear Members of the Reform Committee on the Autism Epidemic,

I am the father of a 27-month-old boy who was recently diagnosed with autism. There is mounting evidence that vaccinations may have a connection to the onset of this neurological disorder. I have seen this connection first hand with my son. I have video taped my son's development sporadically since his birth. He has not spoken one word in this entire time. He also does not point, shows bizarre ritualistic behaviors, has little eye contact (even with his parents), and shows no desire to interact with his peers.

There are treatments available for Josh. The one treatment that shows the most promise of helping him is called early intensive behavioral intervention. This requires therapy of approximately 40 hours a week for at least three years. As you can imagine, this is quite expensive (estimates range from $20,000.00 to $50,000.00 per year.) I am currently not receiving funds from my insurance provider and may be receiving up to $2,500.00 from county resources. Obviously, there is quite a large sum of money left over to cover Josh's necessary treatments.

Because the drug companies had knowledge of possible side effects to immunizations and knowingly ignored them I feel they should be held accountable for their actions.

I urge you to OPPOSE S2053, known as the Frist Bill.

This Bill was written in opposition to HR3741. HR3741 will greatly benefit families like mine. The ones who benefit most from S2053 are the large pharmaceutical companies.

Autism Spectrum disorder is typically not diagnosed until age 3 to 6. The current National Vaccine Injury Compensation Program (NVICP) requires that a claim be filed within 3 years of onset of injury. Due to the misunderstanding of Autism Spectrum Disorders and especially regressive autism, many parents are unaware until years later, when appropriate tests are completed, that the MMR vaccine in fact damaged their child. This excludes them from NVICP and denies them financial compensation for their child whose injury is a life long severe and debilitating condition.

HR3741 allows families like mine to care for their children in a necessary manner. S2053 will severely undermine this bill.

If these children are not given the necessary treatment early and correctly they will, in all likelihood, be dependant on government funding for the rest of their lives. Most will be institutionalized, costing millions of dollars over the course of their lives. What is also troubling is that autism spectrum disorders are increasing exponentially. Autism is the third most common childhood disease in children today. Luckily, through the proper treatment many of these children can lead full and productive lives. They will be able to attain jobs and pay taxes rather than live off of other people's taxes.

S2053 will not allow this to happen.

Please support families like mine. Please Oppose S2053.

I would be honored to have you contact me regarding any of the issues I have discussed. I am part of a growing network of parents who are very adamant about protecting their children's rights and well-being.

Please respond to me in writing regarding your stance on S2053. If you support this bill, please explain to me the benefit of this bill for parents of children with autism. If you do not support this bill please accept my heartfelt thanks on behalf of thousands of families affected by autism.

Respectfully yours,

Tony Bavry

[redacted]

AUTISM PLATFORM STATEMENTS

2002 Goal of the Autism Platform Statements

One of the goals of the United States & State Autism Ambassadors is to work with united States and State legislators to improve autism legislation for new, improved, and amended services, programs, resources, research, respite, alternative treatment, therapy, diagnostic professional & Parent training, and educational options for individuals with Autism Spectrum Disorders to improve their quality of life.

It takes one person to lead, one person to assist with change, one person to send a message of unity, of awareness, for our children/individuals, and the ever increasing numbers of individuals with Autism Spectrum Disorders. A message Of One. Together Unified we can make positive changes for individuals with Autism Spectrum Disorders.

Government

We Support:

1. Governmental officials and all legislators to work closely with the United States Autism Ambassadors and individual state autism ambassadors for improved national and state autism legislation for individuals with Autism Spectrum Disorders.
2. Autism Ambassadors to be a yearly part of the United States Autism Congressional Hearings with Representative Dan Burton and other legislative yearly meeting, hearings, where a voice for Autism is necessary.
3. Autism declared as a pandemic (wide spread epidemic) and federal funding
4. Funds earmarked for training by Autism Ambassadors for families of individuals with Autism Spectrum Disorders.
5. Autism Centers Of Excellence in each state for training, treatment, therapy, diagnostic resources, and research options.
6. Nationally implementation of the Autism Action Plan
7. Funds earmarked for research into alternative treatment options for Autism Spectrum Disorders including but not limited to food allergies, diet, vitamins, and minerals.
8. Funds earmarked for non-biased research into the vaccine connection and autism.
9. Recall of all vaccines containing thimerosal due to growing concerns and uncovered original Center for Disease Control (CDC) reports
10. Requiring physicians to give parents choice of separating the Measles, Mumps, and Rubella (MMR) Vaccine due to growing concern
11. Requiring physicians to give parent a choice to not give vaccines with thimerosal. Enforce laws allowing exemption for religious and medical exemptions with Autism Spectrum Disorders. due to growing concerns and uncovered original CDC reports
12. Development of new and improved Autism training, alternative treatment, therapy, diagnostic, alternative, and educational options
13. Worldwide Autism Registry and accurate tabulation of autism statistics from birth to death.
14. New Initiative Programs available for assisting individuals with autism and families for life care plans and ongoing support.

Government

We Oppose:

1. Mandating parents give vaccines regardless of danger of risk of Autism Spectrum Disorders
2. Direct Funding Concept, in which part of money does not go to the individual with autism.
3 Mandating Vaccine removing freedom of choice.

Health

We Support:

1. Autism known as a Pandemic (wide spread epidemic)
2. Autism Action Plan
3. The Official State Autism Ambassador Project.
4. Autism Ambassadors as licensed Iowa Cable Network(ICN) users; for teaching, awareness, and out reach programs and projects as well as alternative options. This unique type of support has never been offered for autism in a support or training form.
5. The Autism Awakening Autism Center of Excellence; Resources, Research, Training, awareness, and out reach programs as well as all other autism programs Autism Awakening oversees.
6. The Autism Spectrum Disorder Waiver
7. Requiring Medical Professionals and State Autism Ambassadors involvement of setting medical policies and standards (including alternative options) for individuals with Autism Spectrum Disorders within each state
8. All Medical Personnel utilizing Autism Awakening Autism brochures, handouts, booklets, and resources for families dealing with autism Spectrum Disorders. Due to shock of diagnosis it is necessary to offer additional materials to take home. With this devastating news. Retention by parents of important information given in office visit is only 40-50% retained.
9. All Medical Professionals referring parents and patients with Autism Spectrum Disorders to Autism Awakening for important autism first steps and Parents Autism Action Plan after diagnosis to give parents and patients a good start.
10. Off Label Prescriptions: Including vitamins and minerals utilized with alternative treatment of Autism Spectrum Disorders.
11. Full access to funding for autism services, and alternative treatment, therapy, training, diagnostic and educational options.

"Autism Known As a Pandemic (Wide Spread Epidemic)"

12. The autism health plan coverage for alternative treatment, training, therapy, and diagnostic options.
13. Mental parity law for autism and other mental health disorders.
14. Comprehensive patient bill of rights for all members including autism spectrum disorders for any health care plan, including elimination of gag rules.
15. The New Charter Rights for Individuals with Autism Spectrum Disorders.
16. Funding for the expanded Autism Awakening Autism Research for prevention and treatment of individuals with Autism Spectrum Disorders.
17. Iowa Autism Registry: volunteer and mandated registering for individuals with autism for better knowledge of autism as a pandemic (wide spread epidemic)
18. Universal single payer national insurance plan
19. Requiring full access by patient (or in the event of death, the executor of estate or next of kin) of all medical records with no exemptions.
20. Development of a safe needle legislation
21. Comprehensive long-term care facilities for autism spectrum disorders as well as other life lasting disorders and illnesses.
22. Increasing respite services for Autism Spectrum Disorders and other life long diseases, disorders, and illnesses.
23. Establish a adequate ratio of workers to clients in all autism services
24. The right of the parent, patient, and Health Care Team to have adequate training for Autism Spectrum Disorders that effects the life long conditions including alternative treatment options. Including improved pay, training, regulation, and accountability for the medical community for autism spectrum disorders.
25. Mandatory yearly amount of credit hours in training for Autism Spectrum Disorders. Currently there is no accountability or mandatory hours needed to serve individuals with autism.
26. The right of the heath care team, parents, and patient to have the primary responsibility for making decisions regarding patient care.
27. The right of the Primary Heath Care Physician/ Pediatrician to make diagnosis for an Autism Spectrum Disorder Patient as well as the right to place at risk for services.
28. The right of the parent and patient to require accountability for training of professionals working with the patient.
29. Required Nutritional training on diet, vi-

tamins, and minerals and the positive outcomes for Autism Spectrum Disorders. (Parent and Medical Perspectives)
30. Expanding and amending all individual, group, HMO, and all other insurance's to coverage for Autism Spectrum Disorders including alternative treatment, therapy, and diagnostic options.
31. Requiring Physicians to give parents choice of separating the Measles, Mumps, and Rubella (MMR) Vaccine due to growing concern
32. Requiring Physicians to give parent a choice to not give vaccines with thimerosal, allowing exemption for religious and medical with Autism Spectrum Disorders.
due to growing concerns and uncovered original CDC reports.
33. Limiting the drug usage of ADD, ADHD, ASD, PDD, PDD-NOS, Aspergers, and all other children and individuals.
34. Full Time School Nurses
35. Life Insurance for Individuals with Autism at all ages.

Health
We Oppose:

1. Manage Care organizations, insurance's HMOs or other, having the right to terminate or raise coverage fees in ways that shift the financial burden to the families or public sector.
2. Budget Cuts to vital Health Care services, or coverage that are deemed medically necessary by the primary physician Governmental, Individual, group, military, Medical Service Plans; which exclude or limit autism services, treatment, therapy, diagnostic options including alternative options.

Education
We Support:

1. Equal Access to students with Autism Spectrum Disorders of all ages, to educational resources in a safe and secure environment free of harassment from all students regardless of medical condition, Title VII protections, sexual orientation, gender identity, or socioeconomic condition.
2. Right of the Parent, Student, and Educational Team to have adequate training for Autism Spectrum Disorders that effects the lifelong conditions and education of students including alternative treatment options.
3. Right to improved pay, training, regulation, and accountability for the educational community for autism spectrum disorders.

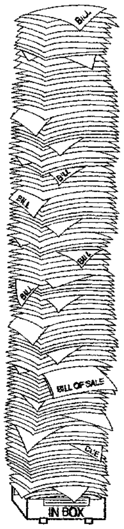
"Equal Access to students with Autism Spectrum Disorders."

4. Educators mandatory yearly amount of credit hours in training for Autism Spectrum Disorders. Currently there is no accountability or mandatory hours needed to serve students with autism
5. Establish an adequate ratio of educators to students in all autism educational services.
6. The right of the parent and student to have a mentoring or shadow associate for the individual with Autism Spectrum Disorders if requested. This helps Social and Communication, etc. Allowing the student to have full access to integrated classes.
7. The right to any facilitated communication for Autism Spectrum Disorders, thus allowing individuals with autism the right to communicate
8. Funding for strengthening programs of students with Autism Spectrum Disorders as well as other special needs programs. Allowing a 10% growth rate.
9. Nationally competitive salaries for special needs teachers, support staff, technology, improved teacher preparation, staff development, and continuing education.
10. Fully Funded IDEA, currently we are only at 18% of the promised 40% increase
11. Expanded Early Childhood and at Risk Programs, as well as Expanding Head Start and public preschool programs for Autism Spectrum Disorders
12. Apprenticeship programs; continuing education, reeducation and retraining for individuals working with Autism Spectrum Disorders.
13. Student Autism Spectrum Disorders Awareness Class in April (Autism Awareness Month) students need sensitivity training to understand what autism is and how they can assist their fellow classmates with autism.
14. Autism Spectrum Disorders studies of early and ongoing educational options by Autism Awakening
15. Equal Access to all learning options by Autism Awakening sent home by schools with Autism Spectrum Disorders Students for their parents review.
16. Strengthening Autism Spectrum Disorder Vocational and Transitional Training and ongoing support.
17. Autism Awakening and schools jointly implementing a Parent-to-Educator training program. Allowing Parents to take a first hand positive approach to teaching educators what works the best with their child at home, and bridges that plain.
18. Students with Autism Spectrum Disorders to have allowed time if needed and a private place for self-stimming

(Sensory issues). As well as training on how to implement sensory diets.
19. Requiring State Special Needs Directors of the Board Of Education's and State Autism Ambassadors involvement of setting educational policies and standards (including alternative options) for individuals with Autism Spectrum Disorders within each state
20. Increase public library funding for autism spectrum disorders resources to parents and professionals
21. Allowing State Autism Ambassadors to be a voice for students with autism in IEP meetings, Board of Education meetings, and PTA meetings, and other educational meetings or purposes.
22. Music Therapy for students with Autism Spectrum Disorders in the school.
23. The Right for Students with Autism Spectrum Disorders to be home schooled if requested, at any age. Home based programs should be approved if requested
24. The right for students with Autism Spectrum Disorders on home based programs to have an adequate amount of educational hours in home.
25. Encouraged Canine therapy for relaxing students with Autism Spectrum Disorders.
26. Continuing Education for individuals with Autism in HCS, ICFMR, MR, CLASS, or other special programs in lieu of adult daycare.
27. Care Plans that allow the individual the choice, allowing the individual with autism to help make a decision on choices for care, medical, and other options.

Education
We Oppose:

1. All attempts to limit any academic freedoms for students with Autism Spectrum Disorders
2. Detention, Time outs, or any other mode of reprimanding of students with Autism Spectrum Disorders for Sensory issues, Self Stimming Behaviors, or lack of Social Cues.
3. School weigh-ins of students with Autism Spectrum Disorders on Special diets for health, safety, and food allergies or otherwise pressuring or drilling of parent by educational personal regarding the students special diet unnecessarily, since the medical professionals are in control of monitoring of the diet.
4. Schools, Educational Personnel, or other educational personal demanding, mandating, or pressuring parents of students with Autism Spectrum Disorders into administering vaccines or psychotropic drugs, otherwise student is forced to stay home from school.
5. Students with Autism Spectrum Disorders turned down for home schooling because of the medical condition or lack of social integration of Autism Spectrum Disorders



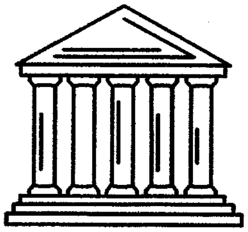
"Autism Ambassadors as ICN Licensed Users."

Criminal Justice
We Support:

1. Requiring Criminal Justice, Police officers, and other law enforcement personal and State Autism Ambassadors involvement of setting Criminal Justice policies and standards (including alternative options) for individuals with Autism Spectrum Disorders within each state
2. Mandating a minimal amount of educational credits on Autism Spectrum Disorders in conjunction with Autism Awakening and the Autism Ambassadors Autism Action Plan and awareness training for law enforcement.

Criminal Justice
We Oppose:

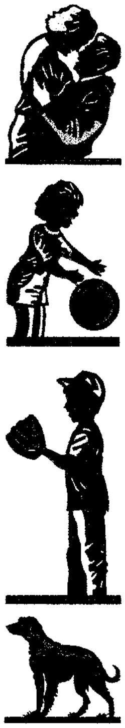
1. Unnecessary force when dealing with an individual with Autism Spectrum Disorders
2. Unnecessary restraint when dealing with an individual with Autism Spectrum Disorders



Human Resources:
We Support:

1. 20 Hours Adequate Advocacy Training for parents of individuals with autism.
2. Supported Housing Counseling and program support.
3. Home supported independent living skills training for house cleaning, washing cloths, cooking, and other.
4. Wraparound Services for Autism
5. Applied Behavior Analysis for Autism
6. No Penalization for working way out of the welfare system.
7. Higher Tax Deductions for individuals with autism.
8. Full funding for School Breakfast, Lunch, Meals on Wheels, and other programs for those with food allergies, for health and safety.
9. Income guidelines based on Child Income rather then families.
10. New Respite Programs and funding for Emergency Respite.
11. Establishment of a Emergency Assistance Program (EAP), that provides provides grants to families with individuals with autism to pay rent, utilities, essential home repair, or mortgage payment.
12. Adequate funding of Legal Services for individuals with autism and their families.

United States & State Autism Ambassadors



Ambassadors are a unity of people, legislators, organizations, and the public

LD Wedewer, IA and US Autism Ambassador in 2002 had authored 19 new pieces of Autism Legislation.

To Write:
LD Wedewer, IA and US Autism Ambassador
1900 K Street SW
Cedar Rapids, Iowa 52404

To Call: 319-364-2687

E-Mail:
Autism Awakening@aol.com

Web Site:
www.AutismAwakening.com

Autism Ambassadors Insuring that No Child/Individual With Autism Is Left Behind!

We The People, By The People In Order To Form A More Perfect Union For Autism!

DR LINDA STEWART
[redacted]

Dear Honorable Representative of the House,

It is with deepest political concern over our medical health freedoms that I am writing to you today. After close to thirty years (30) of living, studying and working overseas, two years ago I returned with my family to South Florida where my children were born.

My children were vaccinated in Florida. The oldest was 10 weeks premature weighing 2 lbs. and had little chance of survival. The second child was born a strong, healthy, smiling full-term baby. We returned to the Alps in Switzerland where our first born premature baby became strong and powerful with macro-bio foods, homeopathy, flower essences and herbs. He is now a straight A student, speaks several languages, and a very active ski champion/swimmer etc.

The second child began to gradually lose his speech around two years of age, and then gradually had a loss of eye contact, then began to withdraw socially until he finally he just stopped speaking entirely. After seeing 4 or 5 neurologists in three different countries, the testing proved normal (MRIs, EKGs, EEG, Mental retardation, Praeder-Willis, Fragile X, Genetic Impulse, DNA Analysis, Genetic Testing, Vision and Hearing). All fell within normal range, some even brilliant, with an I.Q. measuring at 195.

So, what happened to this child? I began to search and look in earnest and eventually I was lead by contacts in the Government to a program developed by

N.A.S.A. called Bio Resonance that utilizes sound frequencies and waveform to determine brain and immune system functioning. Here, for the first time, I saw, our child was full of mercury, actually with high levels completely off the charts, an allergy to wheat gluten and casein and yeast overgrowth in the gastro-intestinal system. It was verified once again that his I.Q. was genius level. In fact, music is his main concentration and the violin, his first love.

The doctors in Florida have determined and confirmed through blood, urine, stool and hair analysis that my son has high levels of mercury, an allergy to wheat gluten and casein and yeast overgrowth in the G.I. Tract.

These findings prompted me to begin to look at the vaccines and to my dismay I cannot believe what I found.

Every lot number of the vaccines was accounted for and researched. The results concluded levels were over and above Federal regulation percentages in massive amounts.

My son received six vaccines in one day....and the story continues....

I have now a group of over 300 children all poisoned by mercury in our immediate area. If you look at their symptoms they are very similar to the symptoms of mercury poisoning: stereotypical behaviors, delayed speech, sensory abnormalities, toe walking, self-injurious *behaviors, gastrointestinal abnormalities, and cognitive impairments. In addition to their already toxic overload, some of these children are being medicated as well.*

I am continuing my research on a daily basis but in order to confront the issue immediately, I am putting together 4 components of a Consortium to address this matter. I am asking as a citizen of this great country of ours for all House Representatives:

I. **To create and pass legislation to give parents the freedom to choose not mandate immunizations with no add-ons by Bureaucrats** (I will be watching this specifically)

II. **To all Autism Caucus Members – Vaccine Proclamation enclosed** Please read

III. **Any Federal or State Bill involving Autism taking away the Constitutional Rights of its citizens to choose freely, forcing, or through coercion from Iowa to Maine or East to West, I will challenge personally on Federal Conspiracy and Coercion.**

You have my word of honor on this. I thank you for your attention on this political matter.

Sincerely,

Linda Stewart

Linda Stewart

N.B. Enclosed please find for your perusal the Vaccine Ingredients.

VACCINE PROCLAMATION

Make available only poison-free vaccines

Dispose of vaccines on shelves containing Thimerosal

Assist cases of children with brain damage and families with deceased children

Create a federal vaccine compensation board and free-up bureaucratic tie-downs

Review vaccines by an ethical board NOT by vaccines companies

Asking Legislators to support and pass legislation

Stop testing vaccines on the disabled population

To provide FREEDOM for parents to choose NOT mandate immunization (with no add-ons by Bureaucrats)

Vaccines

continued from page 27

What's in It?

In addition to the viral and bacterial RNA or DNA found in vaccines, here is a list of other potential ingredients:

aluminum hydroxide
aluminum phosphate
ammonium sulfate
amphotericin B
animal tissues: pig blood, horse blood, rabbit brain, dog kidney, monkey kidney, chick embryo, chicken egg, duck egg, calf (bovine) serum
betapropiolactone
fetal bovine serum
formaldehyde
formalin
gelatin
glycerol
human diploid cells
hydrolized gelatin
monosodium glutamate (MSG)
neomycin
neomycin sulfate
phenol red indicator
phenoxyethanol (antifreeze)
potassium diphosphate
potassium monophosphate
polymyxin B
polysorbate 20
polysorbate 80
porcine (pig) pancreatic hydrolysate of casein
residual MRC5 proteins
sorbitol
sucrose
thimerosal
tri(n)butylphosphate,
VERO cells, a continuous line of monkey kidney cells
washed sheep red blood cells

1 *Journal of the American Medical Association*, June 2, 1993, Vol 269, No 21, pp. 2765–2768.
2 Wakefield, Andrew FRCS and Montgomery, Scott M. Adverse Drug Reactions 2000,19(4) 1–19.
3 Robert Mendelsohn MD, *"How To Raise a Healthy Child … In Spite of Your Doctor,"* (Chicago: Contemporary Books, 1984), p.216.
4 Centre for Disease Control Morbidity and Mortality *Weekly Report*, 6th June 1986, U.S.A.
5 J. Cherry, *"The New Epidemiology of Measles and Rubella,"* (Hospital Practice, 1980), p. 49.
6 Peter Nathan, *The Nervous System*; Philadelphia: J.B. Lippincott, 1969; p.296.
7 Elaine N. Marieb, *Human Anatomy & Physiology*; Benjamin/Cummings Science Publishing, 1998; p.415.
8 Aschner, M., Aschner, J.L., and Kimelberg, H.K. 1992. "Methylmercury Neurotoxicity and Its Uptake Across the Blood-Brain Barrier." in *The Vulnerable Brain and Environmental Risks*. Volume 2. Toxins in Food. Plenum Press, NY, NY. pp. 3–17.
9 Walsh, William J. "Disordered metal metabolism in Autism Spectrum Disorders", presented at the DAN! 2001 Conference in San Diego, CA, Oct. 6, 2001.

SLW

PACIFIC BAKERY
YEAST-FREE
WHEAT ALTERNATIVES
NO SUGAR OR HONEY,
EGGS OR DAIRY,
BAKING POWDER OR
BAKING SODA
RECOMMENDED FOR
ADD/ADHD
COMPLIES WITH THE
FEINGOLD® PROGRAM

OUR YEAST-FREE GUARANTEE™
If a bakery uses yeast in anything,
it's in everything they make.
That's why Pacific Bakery has never
used yeast and never will!
You get the Yeast-Free Guarantee™
only from Pacific Bakery.
WWW.PACIFICBAKERY.COM

THE CONSORTIUM

ORGANIZATIONAL

All agencies
Alphabetically those persons within with integrity (tired of in-house pettiness)
Review of progress achieved in past by them (org)

PRAGMATIC

Sr. Vivien
Elementary Communication Disorders Pilot School

MEDICAL

Initial list of 12 International Doctors, Researchers and 25 add-ons

POLITICAL

Goal: 300 out of 435
Autism Caucus 158 HR + 4 Senators

Socio-Economic and Political Correlates and Antecedents to Epidemic Autism: Public Health and National Security Concerns Regarding Vaccination as a Possible Weapon of Mass Destruction

By

Leonard G. Horowitz, D.M.D., M.A., M.P.H.
Honorary U.S. Autism Ambassador, State of Idaho

Prepared for Members of the U.S. Congress,
Committee on Government Reform Hearing on
Vaccines as a Risk Factor for Autism,
April 18, 2002,
Washington, D.C., U.S.A.

The tragedies of September 11, 2001 have placed you, our leaders in Congress, on special alert. Commissioned as you are to defend Americans and U.S. national security against all foreign and domestic threats, you have much to consider. This day you assemble to discuss the great and grave likelihood that disease prevention through vaccinations is violently backfiring—dramatically increasing mortality and morbidity especially among America's youngest citizens. As you focus these hearings on our nation's most established, generally accepted, public health practice of vaccination, and its links to skyrocketing rates of autism and brain damage in children, this submission and petition raises the spectre that such devastating impacts on our nation's youth, is not simply the result of pharmaceutical company and regulatory agency oversights. Nor can gross negligence fully explain what you are about to consider. Rather, for the sake of families across this great nation, I would hope these hearings might diagnose, that is, see through to the root cause of what is, far more than a medical/scientific dilemma, a socio-political imposition.

Let me explain what I mean by autism, and other vaccine induced injuries, being socio-political impositions, by drawing on the fundamental medical tenant that effective treatment must be directed by accurate diagnosis of, ideally, the root cause of the disorder. As the scientific evidence accumulates revealing more definitive links between a broad array of neurological and/or brain injuries, that other witnesses before this esteemed committee have so adequately testified, these facts reveal a more insidious likelihood as a root cause of autism—one that delivers the gravest warning, and without exaggerating, the most urgent threat to U.S. national security that our nation has ever seen. What threatens is the possibility that pharmaceutical industry originated afflictions, such as autism, produced as a result of "prevention" in medicine, are symptomatic of a deeper degeneracy within the industry itself. This thesis, advanced for your focused attention and remediation, attributes the root cause of this epidemic to a multi-national corporate pathology that transcends common iatrogenesis (i.e., physician induced illness) to effectively express the ideology of what might be best termed "iatrogenocide." This term, genocide, is not used here as a sensational adjective for shock value. Given the evidence before this committee, this term most suitably describes this epidemic's etiology. Genocide is simply defined as the mass killing of people, human resources, including children, for economic, political and/or ideological reasons.

Obviously, in diagnosing and effectively treating the root cause(s) of vaccine-induced "iatrogenocide," relevant historic and scientific facts must be brought to bear on the problem, including the socio-political and economic correlates and antecedents of the vaccine injuries such as autism. When one does this, that is, holistically examines the evolution, number, and extent of catastrophic vaccine-linked epidemics, a conspiracy by drug makers becomes very apparent to anyone with eyes to see documents evidencing such larger truths.

In my capacity as an Honorary U.S. Autism Ambassador from the State of Idaho, a public health professional by training, and veteran independent investigator with expertise in medical sociology and infectious disease research, I have unfortunately, over the past two decades, grown accustomed to instances of poor decision-making, gross negligence, and downright cover-ups in safety oversight and pharmaceutical industry control in the vaccine arena. Many of these I have submitted to this committee upon the request of Chairman Dan Burton's office in the form of my national bestselling textbook, *Emerging Viruses: AIDS & Ebola—Nature, Accident or Intentional?* (Tetrahedron Publishing Group, 1998; 1-888-508-4787)that is summarized in the attached peer reviewed article published in the journal of *Medical Hypothesis* last May (2001;56;5:677-686) detailing largely ignored links between the polio and hepatitis B vaccine programs of the 1960s and 1970s, and the AIDS and hepatitis epidemics devastating global populations today. Additionally reviewed in these publications are studies linking various cancer and autoimmune disease epidemics, to the institutionalized, and increasingly legislated, practice of vaccination.

Vaccine ingredients, I might emphasize, including the toxic metals mercury and aluminum—linked to further brain damage in Alzheimer's disease, and common vaccine preservatives including corpse-conditioning formaldehyde and formalin, present biological and chemical toxins, and other agents of mass destruction, such as viruses and bacteria, and foreign species of DNA, RNA, and proteins, that might be considered potential, if not actual, "biological weapons" due to their molecular and genetic proximity to deadly infectious agents known to every advanced biological weapons arsenal throughout the world.

In essence, I leave for your accounting displeasure, the likelihood that our most trusted public health preventative practice—vaccinating every American against infectious diseases—offers the greatest potential for harm, if not direct sabotage, in delivering a wide array of biological and chemical threats to this nation's people. Given our collective concerns regarding chemo-toxic environments, current threats posed by biological and chemical warfare, and terrorists prone to wield such weapons of mass destruction, it is especially ironic that the immunization method that has gained such widespread acceptance and scientific respect presents one of the greatest threats to public health, and even national security, that our country has ever seen.

I urge you to consider autism, during this hearing, in this larger diagnostic light, as merely a symptom of a deeper disorder, one that might also explain the difficulties this committee has repeatedly experienced impacting an industry whose practices underlie (that is, undermine or assure) the health and safety of all Americans. This deeper industry-wide derangement involves both economics and ideology reflected on every U.S. dollar bill adjacent the words "Nuvus Ordo Seclorum"—a phrase that relays the concept that a new order of things, including global economies, can best evolve from well-managed chaos, like that emanating from disease induction precipitated by vaccination followed by pharmaceutical prescribed control. In this context, autism might be seen, along with myriad vaccine induced injuries, as the signs and symptoms of what military–medical industrialists, in communion with defense department officials, consider an outstanding option for increased social, political, and population control. This is called "non-lethal warfare," though it can be highly lethal with increasing exposures and accumulating toxicity over time.

Let me explain by providing some cogent examples of this pharmaceutical industry-wide menace, that apparently operates above the law, and beyond even your legislative control, as evidence by this committee's earlier hearings:

Last December, for instance, your Committee on Government Reform considered the inadequacies of "The National Vaccine Injury Compensation Program." You determined that, indeed, much progress was required to effectively respond to the rapidly growing legions of vaccine injured persons and their families. Yet, today, little changes appear to have been implemented on behalf of millions of rejected victims whose cases, and calls for compensation, continue to be simply denied and coldly dismissed.

In July of 2000, this congressional committee considered mercury-related vaccine toxicity. You were instrumental in prompting national recognition of such risks, and the elimination of this neurodegerative ingredient (i.e., thimerosal) from vaccines in production. Yet, despite these advances, reputable sources indicate stockpiled vaccines containing mercury are still being distributed in the United States, and increasingly, from the United States to underdeveloped nations. This notion of exporting biologically and chemically induced ailments to the rest of the world is especially troubling for its future implications on foreign relations; particularly in the wake of America's ongoing non-compliance with the United Nations sponsored biological and chemical weapons treaty intended to reduce such threats, and our current "War on Terrorism," which has increasingly isolated this mighty militarized nation from the rest of the civilized world.

A final compelling example comes from your inconsequential rebuke of the U.S. Department of Defense concerning the manufacture and sale of inadequately tested, highly risky, and largely ineffective anthrax vaccines manufactured by BioPort Corporation of Lansing, Michigan following your two October, 2000 hearings. Bioport's Chief Operating Officer and Director, Robert C. Myers, DVM, you may recall, addressed the joint meeting of the Senate Veterans Affairs Committee and the Senate Appropriations Committee that included the Subcommittee on Labor, Health and Human Services (HHS), Education and Related Agencies, on March 16, 1999 on behalf of the Defense Department's Joint Vaccine Acquisition Program (JVAP) administered by the Battelle Memorial Institute (BMI) in Ohio. During his testimony, Mr. Myers urged appropriations be set aside for his company's program, and two separate stockpiles of anthrax and smallpox vaccines for national defense.

You may not know that in April, 1998, OraVax (currently a Hoechst/Acambis) Corporation Vice President, Dr. Thomas Monath met with President Clinton, New York's Emergency Management Director, Jerry Hauer, Rockefeller University president emeritus and American Type Culture Collection (ATCC) curator, Dr. Joshua Lederberg, CIA Director John Deutsch, and government biological weapons expert William C. Patrick, III, to negotiate the first of several multimillion dollar anthrax, smallpox, and West Nile virus vaccine contracts. William C. Patrick, III, America's leading military anthrax expert, was implicated in recent months as a chief suspect in the mysterious anthrax mailings.

According to *New York Times* reporters William Broad and Judith Miller, seven scientists endorsed stockpiling these vaccines. These included "two men who stood to gain financially from the decision. . . ." These men included Dr. Monath and Dr. J. Craig Venter, president of The Institute for Genomic Research near Washington working closely with BioPort and the BMI on anthrax genetics, and Baxter Corporation for smallpox vaccine. The *Times* reported that despite widespread descent in the scientific community regarding this investment, these privileged few individuals and organization stood to financially gain most from these appropriations.

Curiously, a few months ago, in the wake of the anthrax mailings that targeted some of your own colleagues here on Capitol Hill, the *New York Times* and *Washington Post* announced that pharmaceutical companies were among the chief suspects in the FBI's investigation, and that BMI, a chief supplier and administrator of Dugway Proving Grounds' airborne biological weapons testing laboratories, illegally produced under a Central Intelligence Agency (CIA) contract called project "Clear Vision," the specific Ames strain of hyper-concentrated, electro-magnetized, silica-weaponized anthrax that somehow found its way from these laboratories to your mail rooms. William Patrick, III was apparently contracted by both the CIA and BMI to compile a report on the ramifications of mailing such a hyperweaponized anthrax, months before the initial bioterrorist attacks. Soon after the mailings and bioterror, HHS Secretary Tommy Thompson heralded an unprecedented half-billion dollars worth of anthrax and smallpox vaccine orders in keeping with Dr. Myers's 1999 request.

Congressman, is there really any wonder why your opposition to military anthrax contracts, and vaccination cessation demands, were flippantly disregarded by Pentagon officials with certain ties to vaccine makers?

In essence, your positive efforts have done little, if anything, to curtail the threats posed by vaccine industrialists pursuing their lucrative contracts.

President Dwight Eisenhower summarized this threat best in 1961 during his Farewell Address to the Nation. Regarding the greatest risk to America and the free world, he cautioned, "beware of the military-industrial complex" and the councils of government wherein political and economic decisions are made and pressures are brought to bear on unwitting law makers and citizens.

Representing American grassroots antivaccination activists nationwide as I do, free from the influence or bias of pharmaceutical company grants and industry lobbyists, I appreciate this opportunity to deliver this uncensored challenge and subsequent message of hope.

Your challenge here in diagnosing and effectively treating this nation's autism epidemic is compounded by a rapidly growing public cynicism regarding your legislative impotency. As recent national polls indicate, the fewist Americans today trust government, their governing officials, to intercede on their behalf as guardians against corporate negligence and, even worse, vaccine industry malfeasance. Thousands of Americans wish to know why you simply don't rescind the "National Childhood Vaccine Injury Act of 1986"—legislation that effectively protects vaccine makers against injury claims, leaving hundreds of thousands, if not millions, of devastated families to fend for themselves against a compensation program admittedly inadequate at best. Others wish to know (despite efforts in the last years to improve vaccine injury reporting), given the inadequacy of injury-reporting systems and data, and the resulting inability to perform required risk/benefit analysis for all vaccinations (i.e., the scientific yardstick upon which all public health practices must be measured to have the policy be considered safe), why are vaccines allowed to be administered at all?

With all due respect, to make this point resonate within these walls of Congress, I present to you two graphical depictions of the public's perception of your legislative impotence in contrast to pressures placed upon you by special interests heavily invested in the vaccine industry. Published by the Whitney Museum with support from The Henry Luce Foundation, The Andrew W. Mellon Foundation, and others, this artwork depicts your ilk with right hands pledging allegiance to the flag of the United States of America with left hands engaged in mutual masturbation. Nude below the waist, this National Endowment for the Arts funded congressional representation shows law makers skirting vital issues of public concern and national security for payoffs from pork-barrel politics as usual.

The second exhibit, openly displayed at the residence of this artist's leading benefactor, and German diplomatic associate of Dr. Henry Kissinger, Mr. Klaus Groenke, portrays sheep looking to their leaders who walk the plank to their demise on the hard rocks below. The people, or should we say "sheeple," simply follow suit.

Indeed, these are difficult images to consider, especially reflecting on the more troublesome political reality about which they speak.

Again, I emphasize the apparent connections between those who have largely sponsored this "art" and those who heavily influence, if not generally control, the manufacture of vaccines and the current plagues of autism, autoimmune diseases, certain cancers, and more. We can thank, for instance, Nelson Rockefeller's protégé, and leading Merck pharmaceutical company advisor, Dr. Kissinger, for principally spiriting the nuclear arms race of the Cold War, and the biological weapons race shortly thereafter. I wonder how many of you have read Dr. Kissinger's 1972 treatise, National Secret Security Memorandum 200, that called for massive Third World depopulation?

In closing, I am pleased to offer hope in providing the following petition that I present on behalf of tens of thousands of Americans, and numerous allied organizations in the growing vaccination reconsideration movement—parties who still trust that collectively we can re-secure our lives, liberties and pursuits of education and labor without forced vaccinations, and with increasing access to alternatives in health care.

In summary, medical physicians learn to base their pharmaceutical prescriptions on accurate diagnosis. So must members of the U.S. Congress base legislative treatments on accurate diagnoses regarding the etiology of today's most pressing problems. Such is the case with vaccine injuries like autism.

The "slash, burn and poison" approach dominating health care today should also be applied to direct legislative reforms of the vaccine industry. The attached petition requests that you *slash* government funding for projects dominated by the petrochemical–pharmaceutical cartel, closing their legal loopholes while directing support to more independent investigators, laboratories, and companies; *burn* alliances between federal agents and agencies purported to be acting on the public's behalf while obviously biased by allegiances to special pharmaceutical interests; and *poison* through your activism, the notion that magic pills and potions can be swallowed to cure every ill, when an ounce of life-style change for prevention, including choices for better nutrition and hygiene, has proven itself time after time to be worth far more than a pound of cure. This is also true in the realm of boosting natural immunity against the most common and dangerous infectious diseases. Typically those who succumb to "vaccine-preventable diseases" are inordinately those at higher risk of infection, mortality, and morbidity due to socio-economic impositions and life-style factors within control of the general population.

Submitted in the interest of public health and safety by:

Leonard G. Horowitz, D.M.D., M.A., M.P.H.
Honorary U.S. Autism Ambassador, State of Idaho
Past Chairman, Political Committee, National Health Federation, and
President and Publisher, Tetrahedron Publishing Group
Sandpoint, Idaho

Mister (Madame) Chairman, members of the Committee (Subcommittee):

I am James Raymond Donnelly. My son, Christian Alexander Donnelly, is autistic. He will never be self-sufficient, never be productive. He will always be a burden. Yet he was not born this way. Quite the contrary. For the first eighteen months of his life, he was a healthy, happy little boy and the joy of our life. He was born on November 13, 1992, weighing eight-pounds, four-ounces. He crawled, he walked, he climbed. He had lots of little friends and enjoyed being with them. We played and he mimicked us. We made faces, he made faces. We played games, and he sang songs as quickly as we could teach them to him. I remember once when our little family went to Chicago. He wasn't even a year and a half old. We were at a stop sign, and counting down turns to a friend's house. His mom said, "That's one." And Alexander piped up: "two...three...four... five...six." And so on. We thought we had the perfect child. Don't all parents think so?

All that changed. It changed on May 9, 1994. What September 11, 2001, was to all Americans is what May 9, 1994, was to us.

On that day Alexander's mom took him to the health department for a series of vaccines recommended by his pediatrician. Alexander received seven vaccines that day, including HbPV, polio, DTP, and MMR. We had absolutely no reason to think Alexander would receive anything but safe, effective drugs. How sadly mistaken we were.

Alexander cried the next few nights and was grouchy for several days. Then he became ill. We took the first appointment with his pediatrician we could get, on May 18, 1994. By that time, Alexander was suffering from chest congestion, coughing, green nasal drainage, and fever. The doctor treated him with a regimen of antibiotics. Within a week the drugs seemed to relieve the symptoms.

But from then on, Alexander was a very different child. He did not interact with us or his friends as much as he had previously. He did not demonstrate any further improvement in social or learning skills. We thought perhaps he was reacting to having a new brother who was born around that time. In October, 1996, Dr. Peter Tanguay, an expert on autism, gave us the real answer. Our child, Alexander, was autistic.

As time went on, Alexander didn't improve at all. He began holding his hands on his ears and squealing at a high and uncomfortably loud pitch. He refused to stay inside the house and would leave frequently. We were forced to put dead-bolt locks on every door in the house and even nail the windows shut. He would frequently remove his clothing no matter where he was and run around naked. In fact, he still removes his shirts and will even put his coat on over his bare upper torso in the wintertime. We finally potty trained Alexander when he was nearly six years old. Since the day he received his vaccines, he has not been able to answer a question with anything other than a 'yes' or 'no'. In the last few months he has been on a diet exclusive of wheat and dairy products. We believe that is why he has recently been able to use small assortment of complete sentences.

He hasn't made a friend since he received the shots. He remains isolated. He tries to interact with other children, but he is unable to do so with anything other than repetitious questions. He is invariably unsuccessful. He is constantly frustrated. He has trouble asking for the things he wants and needs. He has difficulty controlling his behavior and becomes violently angry when we can't understand what he is saying. He spends a great deal of his time dropping small items behind furniture and using straight objects to follow grains in wood furniture. He likes to watch the same movies over and over. He loves the violin, but can't comprehend instruction well enough to hold one properly, much less learn to play. He loves to play on swings, as the motion appears to stimulate him somehow. We believe these are all the result of a perceptual incapacity that he's trying to compensate for. He still has the same level of development in the third grade that he did in the first. It's clear the school is moving him along because of his age. His teachers do not have adequate training or resources to provide him the education he so desperately needs--and to which he is entitled by law.

Then we arrive at the emotional ruin and financial loss that autism creates for us and for many others. Parents are facing bankruptcy as the result of paying huge amounts for the medical and educational needs of these children. Insurance companies choose not to cover these expenses. Public schools are not adequately funded to provide for their educational needs.

Chances are Alexander will outlive his mother and me. He'll need to be cared for as an adult. Millions of other autistic children will need to be cared for, too. There is a 10-17% annual rise in the frequency of autism.

But the impact on an autistic child's family goes well beyond the financial burden. Siblings are denied many opportunities because families are unable to go anyplace in public because it's so difficult to control the autistic child's behavior. In my case, my younger son Brendan can't participate in sports unless we can find a baby-sitter for Alexander so we can take him to his ball games. In our case, too, the financial strain led Alexander's mother and me to divorce. Both of our children suffer emotionally as a result.

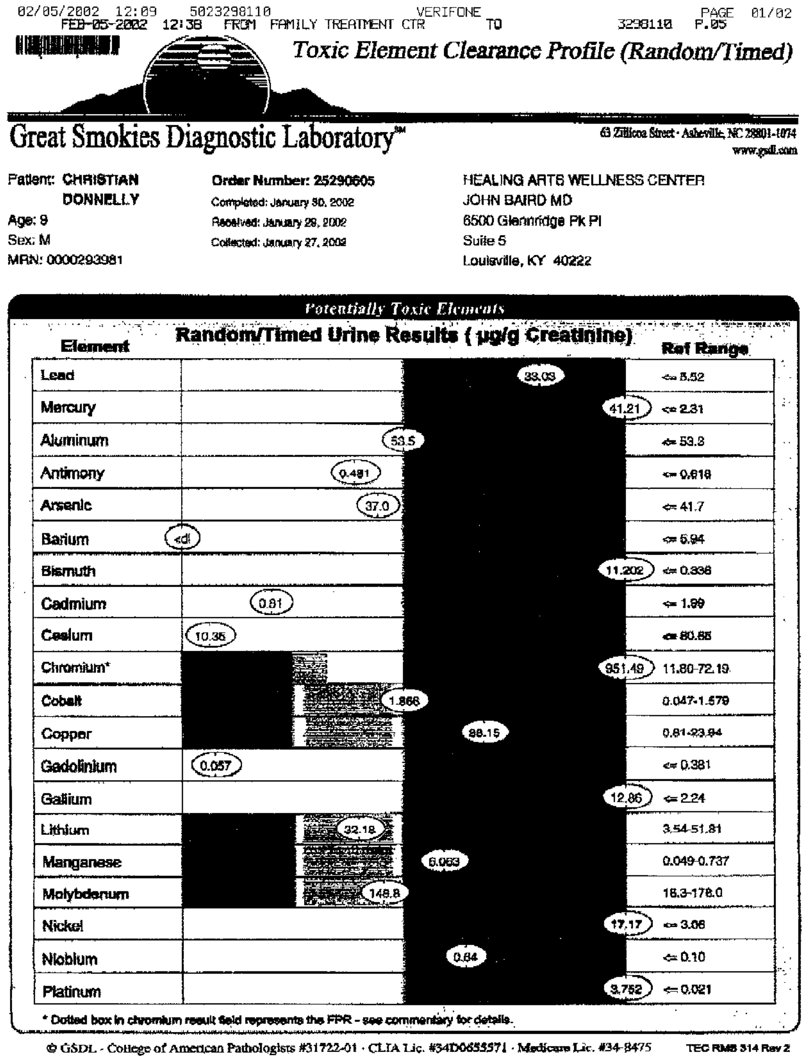
I blame the vaccines Alexander received for all of this. Vaccines, in and of themselves, are blessings, for all of us. I believe the problem lies in the manufacture and administration of these drugs. I understand they are preserved with an untested form of mercury. I would think that mercury of any kind is unacceptable in vaccines. This year, seven years after his shots, Alexander underwent a metals toxicity test, which revealed that mercury levels in his body exceeded 20 times the EPA's established safety margin. This is a reflection of Alexander's apparent over-exposure to thimerosal.

Combining drugs to deliver them with one injection, the MMR vaccine for example, is risky. I believe that administering the Hepatitis-B vaccine at birth creates a greater risk than the benefit it provides as the baby's body already has a multitude of adjustments to make when it is born.

It is also clear that some children may have a genetic predisposition not to be tolerant of the bodily insult the vaccine creates. Knowing this, we should take measures to isolate these factors and avoid the reckless administration that has become so prevalent. Parents should also have a choice on whether to administer these vaccines and they should be made aware of the possible risk to which they are subjecting their children. By not addressing the risk, we're essentially playing "Russian Roulette" with our children's lives. We're not only risking autism, but ADD, ADHD, behavioral problems and other neurological disorders.

A cynic would view with suspicion the uncomfortably close relationship between the CDC and FDA and the drug companies who are directly affected by the federal agencies' policies. When the federal agencies accept drug manufacturers' money, how can they act impartially and in the best interests of children? It can promote an environment of partiality for the parties providing these dollars. In other arenas, this might be considered to be an abuse of trust or possibly even bribery.

But let me return to my son, Alexander. Autism is often considered as a genetic disorder that is present from birth. But if Alexander were simply "wired wrong", he would not have developed normally for the first eighteen months of his life. Something triggered his condition. I believe it was the untested mercury in the vaccines he received. Now the best years of his life are long gone. And Alexander is not alone. The impact on families goes beyond the comprehension of those who don't have to live with autism. The implications are enormous. Our children are becoming tax-services users instead of taxpayers. Our families are going broke, which is affecting our economy. The drug companies are making billions of dollars loading our children up with an increasing number of pharmaceuticals and creating a whole new source of wealth from the treatments for the disorders created by the questionable vaccines. New treatment options and intensive research are mandatory in finding answers to this dilemma. Insurance companies need to be required to cover these disorders. A reduction in the sheer numbers of the vaccines administered needs to be implemented until more thorough research is completed. Education of medical professionals concerning the potential dangers involved in the present use of vaccines should be a requirement of government and licensure agencies. Parents should be made aware of these possibilities and given a choice on how or whether to administer these vaccines to their children. Implementation of these measures would certainly reduce the rate of new instances of autism, which would indeed be a step in the right direction.



02/05/2002 12:09 5023298110 VERIFONE PAGE 01/02
FEB-05-2002 12:38 FROM FAMILY TREATMENT CTR TO 3298110 P.05

Toxic Element Clearance Profile (Random/Timed)

Great Smokies Diagnostic Laboratory℠

63 Zillicoa Street · Asheville, NC 28801-1074
www.gsdl.com

Patient: **CHRISTIAN DONNELLY**
Age: 9
Sex: M
MRN: 0000293981

Order Number: 25290605
Completed: January 30, 2002
Received: January 29, 2002
Collected: January 27, 2002

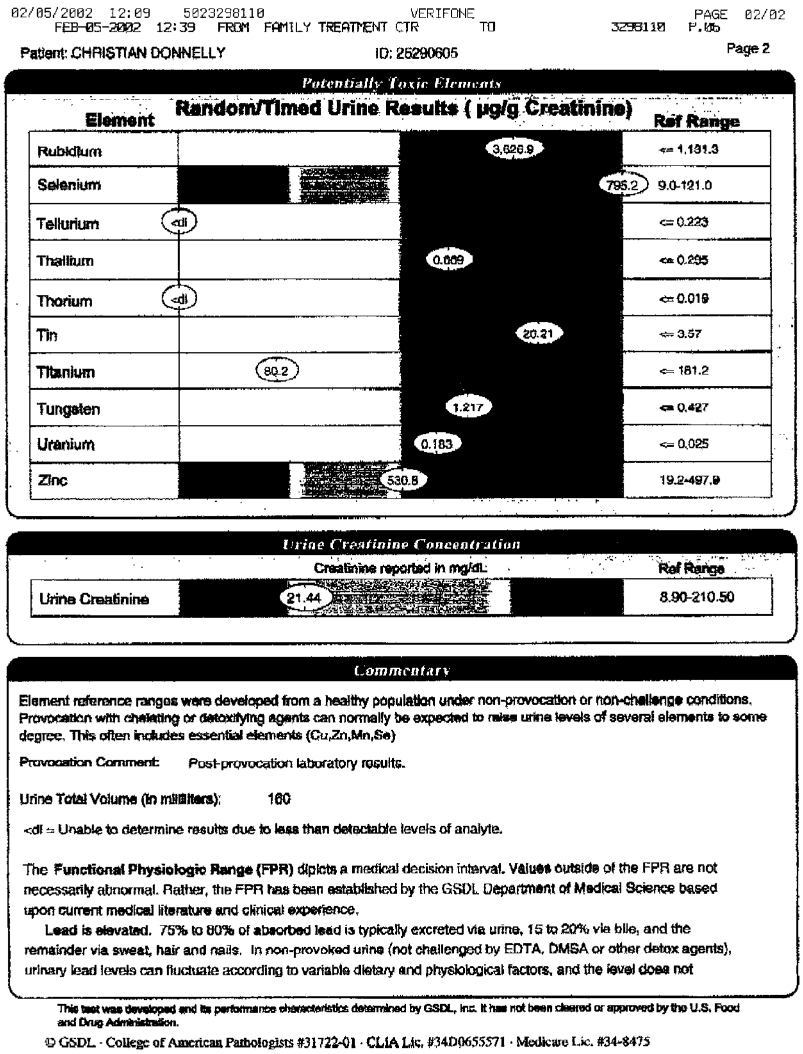
HEALING ARTS WELLNESS CENTER
JOHN BAIRD MD
6500 Glenridge Pk Pl
Suite 5
Louisville, KY 40222

Potentially Toxic Elements

Element	**Random/Timed Urine Results (µg/g Creatinine)**	**Ref Range**
Lead	33.03	<= 5.52
Mercury	41.21	<= 2.31
Aluminum	53.5	<= 53.3
Antimony	0.481	<= 0.618
Arsenic	37.0	<= 41.7
Barium	<dl	<= 5.94
Bismuth	11.202	<= 0.336
Cadmium	0.81	<= 1.99
Cesium	10.35	<= 80.88
Chromium*	951.49	11.80-72.19
Cobalt	1.866	0.047-1.579
Copper	88.15	0.81-23.94
Gadolinium	0.057	<= 0.381
Gallium	12.86	<= 2.24
Lithium	32.18	3.54-51.81
Manganese	6.063	0.049-0.737
Molybdenum	148.8	18.3-178.0
Nickel	17.17	<= 3.06
Niobium	0.84	<= 0.10
Platinum	3.752	<= 0.021

* Dotted box in chromium result field represents the FPR – see commentary for details.

© GSDL - College of American Pathologists #31722-01 · CLIA Lic. #34D0655571 · Medicare Lic. #34-8475 TEC RMB 314 Rev 2



```
02/05/2002  12:09     5023298110                    VERIFONE                              PAGE  02/02
      FEB-05-2002  12:39   FROM  FAMILY TREATMENT CTR          TO                  3298110   P.05
```

Patient: CHRISTIAN DONNELLY ID: 25290605 Page 2

Potentially Toxic Elements

Element	Random/Timed Urine Results (µg/g Creatinine)	Ref Range
Rubidium	3,626.9	<= 1,131.3
Selenium	795.2	9.0-121.0
Tellurium	<dl	<= 0.223
Thallium	0.669	<= 0.295
Thorium	<dl	<= 0.019
Tin	20.21	<= 3.57
Titanium	80.2	<= 181.2
Tungsten	1.217	<= 0.427
Uranium	0.183	<= 0.025
Zinc	530.8	19.2-497.9

Urine Creatinine Concentration

	Creatinine reported in mg/dL	Ref Range
Urine Creatinine	21.44	8.90-210.50

Commentary

Element reference ranges were developed from a healthy population under non-provocation or non-challenge conditions. Provocation with chelating or detoxifying agents can normally be expected to raise urine levels of several elements to some degree. This often includes essential elements (Cu,Zn,Mn,Se)

Provocation Comment: Post-provocation laboratory results.

Urine Total Volume (in milliliters): 160

<dl = Unable to determine results due to less than detectable levels of analyte.

The **Functional Physiologic Range (FPR)** depicts a medical decision interval. **Values** outside of the FPR are not necessarily abnormal. Rather, the FPR has been established by the GSDL Department of Medical Science based upon current medical literature and clinical experience.

Lead is elevated. 75% to 80% of absorbed lead is typically excreted via urine, 15 to 20% via bile, and the remainder via sweat, hair and nails. In non-provoked urine (not challenged by EDTA, DMSA or other detox agents), urinary lead levels can fluctuate according to variable dietary and physiological factors, and the level does not

This test was developed and its performance characteristics determined by GSDL, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration.

© GSDL · College of American Pathologists #31722-01 · CLIA Lic. #34D0655571 · Medicare Lic. #34-8475

Name "Alexander" Donnelly Birth Date 11-13-92 Date First Seen 5-18-94
Race Sex Insurance
Hospital Address Phone
Obstetrician Address Phone
Referred by
Father's Name Address Phone
Mother's Name Address Phone

20963

FAMILY HISTORY

	Age	Health	Allergies
Mother			
Father			
Sibling			
Sibling			
Sibling			

Miscarriage Month Cause
Tuberculosis TBC Contacts
Allergy
Diabetes Convulsive Disease
Mother's Blood Type RH Baby's Blood Type

BIRTH AND DEVELOPMENT

Term Delivery Birth Weight
Condition at Birth Apgar Score
Condition 1st Week
Feeding Cyanosis
Convulsions Jaundice
Sat Up Stood Walked Words
Short Sentences First Teeth Bladder Bowel

RECORDS RELEASED
4-27-00

FEEDING HISTORY

Breast Formula Vitamins
Primary Drinking Water Supply: ☐ Well ☐ City/Municipal ☐ Bottle Area Water Fluoride Level: ☐ Inadequate ☐ Adequate ☐ Unknown
Fluoride Supplements: *Topical* ☐ Rinse ☐ Gel ☐ Paste *Systemic* ☐ Vitamin/Fluoride Supplement ☐ Fluoride-Only Supplement
Soft Food Present Diet Feeding Habits
Appetite Likes Dislikes
Vomiting Stools Sensitivity Hives

IMMUNIZATION AND SKIN TESTING

	DATE	DATE	DATE	DATE	DATE	DATE
DTP	1/19/93	3/23/93	7/27/93	5/9/94		
OPV	1/19/93	3/23/93	5/9/94			
HbPV (Haemophilus b Polysaccharide Vaccine)	1/19/93	3/23/93	7/27/93	5/9/94		
MMR	5/9/94					
Tuberculin						
DT			OTHER			
HEP B Other	11/14/92	12/18/92	8/22/93			

ILLNESSES

Pertussis	
Measles	
Rubella	
Mumps	
Chickenpox	4/96
Scarlet Fever	
Diphtheria	
Operations	
T. and A.	
Allergy	
Appendix	
Glands	
Rheumatic Fever	
Otitis	
Colds	
Tonsillitis	
Convulsions	
Constipation	
Diarrhea	
Asthma	

Provided courtesy of
Mead Johnson
NUTRITIONALS
Enfamil® ProSobee® Nutramigen®
Pregestimil® Ricelyte™ POLY·VI·FLOR® Tempra®

Name Christian Alexander Donnelly Birth date 11-13-92

Height____ Weight____ Temperature____

Head____

Eyes____

Ears____

Nose____

Mouth____

Teeth____

Vitamin/fluoride supplement needed: Yes ☐ No ☐

Throat____

Neck NKA to med.

Chest hosp. ō

Heart recur ill ō

PMX - Hemming[illegible] [illegible]

Lungs____

Abdomen____

Genitalia____

Extremities____

Skin____

Back____

Adenopathy____

Deep reflexes____

Superficial reflexes____

Nuchal rigidity____

Posture____

Development____

Nourishment____

Vitamin supplement used: Yes ☐ No ☐

Blood count____

Urinalysis____

5-18-94
c/o cough + chest congestion
green nasal drainage, loose BM's,
low grade temp.
wt: 26-15
HEENT - URI
OMR
Chest - croupy
AP: RSR s̄ m
Ventolin ½ tsp q6h
Duricef 125 TID
NHSA

10-31-94
CC: Fever: 102 last 1/2
Temp 101 102 oral mode
ear prob
OND
Drooling
[illegible] None
Yellow [illegible]
OMA [illegible]
[illegible]
Amoxil 125 TID

12-10-94 2yr Visit
Ht 35¾" Wt 38 lb HC 51¼ cm
2% M.lk
PE good [illegible]
Mom
Imm UTD/[illegible]
CBC -

© 1990, Mead Johnson & Company, Evansville, Indiana 47721, U.S.A.

[redacted]

From: [redacted]
Sent: Thursday, May 02, 2002 3:09 PM
To: [redacted]
Subject: Autism Testimony

Chairman Burton, Congressman Waxman and distinguished members of the Committee:

Thank you for the opportunity to present this testimony from the perspective of a parent of a person with autism. I would like to address two issues at this time. The first is the use of physical, mechanical and chemical restraints on people with autism and other disabilities. The second is the reluctance of school districts to provide the services required by the Individuals with Disabilities Education Act.

My wife Jane and I have five children, born between 1970 and 1981. Our fourth child David was born December 30, 1976. He progressed at the same rate as his older siblings until he was around two years old, then he suddenly regressed into the world of autism. Slightly over four years later, on February 22, 1981, his younger brother Jason was born. Jason was extremely intelligent, with an IQ around 150. By the time he was 12 years old he had read every Tom Clancy novel written. His problem was that he could not cope with the confines of a classroom. After numerous suspensions for behavioral issues he was placed on homebound instruction for over a year while the school district and we, as parents looked for a suitable placement could be found. On May 11, 1993 he was placed in a facility in Pennsylvania. This was not the placement we had wanted but the school's choice. The following day we received a phone call from the facility saying that Jason had been involved in an altercation with another resident and had been restrained. The caller said that Jason had passed out and had been taken to the local hospital. He had not passed out, he had stopped breathing. Despite efforts to revive him, he died the following day. The restraint method used was a prone position with his arms held behind his back, while the employee sat, yes sat on the small of his back.

We were under the impression that this had been a rare "accident" and were even told by the facility's attorney at the civil settlement hearing that "At least you will know that something like this will never happen to another child".

We believed that until several years later when a friend told us of a similar event happening it Connecticut. In this case it was an 11-year-old boy. His death lead to an investigative report by the Hartford Courant. (a).

Their report revealed 142 deaths by various forms of restraint. Most of the deaths were of people under the age of 21. Since that time many other such deaths have occurred, including one in January 1998 at the same facility that Jason died at.

After reading the Courant report, I formed a list server on the Internet to discuss these events and to find a way to prevent future deaths.

Hardly a month goes by that another restraint related death does not occur. In March of this year a 22-year-old man with autism was fatally restrained after he walked out of a Kmart without paying for a toy truck that he had picked up. Store security personnel did not restrain him, but staff members from the group home in which he lived did.

This past Saturday a 13-year-old boy in a group home for developmentally disabled youth died as a result of restraint.

As the parents of an autistic adult, we realize that someday our son David will be in someone else's care. How he and other adults with autism will be treated then is a very serious concern for us and many other parents.

An even more shocking discovery I made was that these same restraints that have caused numerous deaths are used in schools as a form of behavior modification. They are not used to prevent injury, but often in a punitive form for non-compliance with the teacher's instruction.

Imagine a child with autism, the definition of which states that they do not relate to situations in the same manner as most "typical" people do, being told, "You can get out of this restraint when you blow your nose properly". Now add in the fact that they may also be fighting to breathe and this child could be in serious trouble.

Many schools and other facilities appear to be primarily concerned with the behavioral aspect of autism. True, some autistic people seem to have violent or aggressive behaviors, but not all of them do. In fact, most of the people with autism I have met are not violent.

In a table from the National Institute of Mental Health entitled "Behavioral Differences of Autistic and Normal Infants" under the heading "Social Interactions", is stated, "Physically attack and injure other without provocation". Just how do infants attack someone?

My second issue, which in some ways is linked to the first, is the reluctance of school districts to provide the services required by the Individuals with Disabilities Education Act.

Through the same list server that deals with restraints and from other email I receive, I constantly hear stories of parents who cannot get the services they need for their children. The list of reasons that schools give borders on the incredible. I recently came across a website that listed some of these excuses. I would like to share some of them with you at this point; (b)

In my IEP meeting, the learning consultant actually told me that my son couldn't attend a specific out of district placement because the school bus driver didn't like to drive on the particular highway on which it was located....

While working to ensure that the audio portion of videos shown in her deaf son's classroom were provided in a format her child could have access to, the teacher involved used the excuse, "I have 30 kids in a classroom, it is hard to make adaptations."

When asking our local school how they would handle our son's education...he is deaf, and was transferring out of a deaf school into a public school, they told me...We don't know of any interpreters so he will have to "wing it" in his classes. And we are still fighting them today.

At an IEP meeting for my 5-year-old daughter I inquired about adding a ramp to the playground equipment. Here are some of the many reasons that were given me for NOT doing it.

"If she could get her walker up on the equipment the other children would have a hard time running around her"

"If we built a ramp then neighborhood children might ride their bikes up here, get hurt and we would be sued"

"Walking up that ramp would just make her too tired to walk back into school" And my favorite.... "I don't know how we would put a ramp on the equipment without making the playground look strange"

We just a received a note that our child's IEP was up for review and as we had been to the last one there was no real need for us to be there.

Objective, under the goal of personal independence: "Johnny will independently cross the street safely, 50% of the time." (Personally, I would be worried about the other 50% of the time.)

I was told repeatedly that it was against the regs for our daughter to have any other problems because of her hearing problem. (Unless of course she was blind or motor impaired.)

When a parent inquired about whether the IDEA Amendments were in effect, a SPED Director replied, "They haven't been grandfathered in yet".

"During the Adaptive PE evaluation he was worn out after 15-20 minutes. I will be seeing him twice a week for 50 minutes a session."

Then, there is what I consider the all-time classic. This was on a parent advocacy list server from Massachusetts.

"We don't have to provide your child with the best education, only an appropriate one". (Isn't anything less than the best *inappropriate*?)

Once again, thank you for the opportunity to express my concerns before your committee.

Richard Tallman

[redacted]

Email [redacted] [redacted]

References

(a) http://courant.ctnow.com/projects/restraint

http://www.ctnow.com/news/local/hc-sp-dmr-1202.special

(b) http://www.listen-up.org/rights/outrageous.htm

Do You Yahoo!?
Yahoo! Health - your guide to health and wellness

[redacted]

From: Chris and Trina Sherman [redacted]
Sent: Thursday, April 18, 2002 12:10 PM
To: [redacted]
Subject: autism testimony

Dear Beth,
I am a mother of a 7 year old autistic child. I had him in public school from age 3 to age 6. Although the school district had an "autism specialist" and claimed to do a variety of education methods they refused to do the only curriculum proven to help children with autism. Applied Behavior Analysis and the newer version called Applied Verbal Behavior were what were recommended to us on a trip to Johns Hopkins hospital and the Kennedy Krieger Institute. Despite our training of the public school teachers and all of our doctor's recommendations the school refused to do any ABA or AVB claiming it was not possible for them to do. Rather than fight the school district in court I home schooled my child AFTER public school each day and on weekends until he was 6 and an opening came up in a private ABA school in Austin. Matthew has made huge gains both with his behavior and in his communication with this AVB method. We met his IEP goals in 3 months that the public school had been working on for 2 years! This private school that uses the AVB method and a one to one ratio costs our family 25k a year. So as you can imagine very few people can afford this school or even to do an in home program at $25 an hour with a 25 hour minimum a week that is recommended. The children in Texas are being denied this educational model not because it is inappropriate but because the school would rather hire untrained aides to baby-sit our kids. Since the aides and teachers lack any knowledge of how to control autistic behavior we are creating a huge society of autistic adults who will never be able to function in our world or hold a job. Yes, training and intense teaching are difficult and expensive, but you don't have enough institutions to hold all of us that are coming. Fix the education system now or pay later it's as simple as that. I had cause to sue my school district, and in retrospect I may have been able to make more of a difference for the kids who cannot afford private school. I am hopeful that with the progress that is being made with autistic children using AVB and ABA and intense teaching that the proof will be in the success of our children. The school districts will no longer be able to claim that ABA and AVB are not effective teaching models. Autism is skyrocketing are you ready?
Yours truly, Trina Sherman Round Rock Texas[redacted]

[redacted]

[redacted]

From: M.GAIL BRUSO [redacted]
Sent: Friday, April 19, 2002 12:17 PM
To: [redacted]
Subject: Autism Testimony

To: [redacted]
From: Gail Bruso

Please add my "vote" to the list advocating school vouchers for use by students with Autism. My very good friend, Britton Holman is an autistic young man who has received barely adequate assistance in the public school system. He would benefit greatly from this program as would others with this handicap.

Thank you for your attention to this matter.
Gail Bruso
[redacted]

[redacted]

From: [redacted]
Sent: Saturday, April 20, 2002 2:26 PM
To: [redacted]
Subject: autism testimony

I have seen friends struggle with their Autisic son for 8 years.

They have exhuasted resources to find care and medical treatment for him to the point that they cannot afford private or individual instruction.

Britton is often left to stem while at school as the teachers seems to be at a loss of how to engage him.

I encourage a "yes" vote for school vouchers for handicap children.

Robin Cole
[redacted]

[redacted]

From: [redacted]
Sent: Saturday, April 20, 2002 2:26 PM
To: [redacted]
Subject: autism testimony

I have seen friends struggle with their Autisic son for 8 years.

They have exhuasted resources to find care and medical treatment for him to the point that they cannot afford private or individual instruction.

Britton is often left to stem while at school as the teachers seems to be at a loss of how to engage him.

I encourage a "yes" vote for school vouchers for handicap children.

Robin Cole
[redacted]

[redacted]

From: [redacted]
Sent: Friday, April 19, 2002 12:17 PM
To: [redacted]
Subject: Autism Testimony

To: [redacted]
From: Gail Bruso

Please add my "vote" to the list advocating school vouchers for use by students with Autism. My very good friend, Britton Holman is an autistic young man who has received barely adequate assistance in the public school system. He would benefit greatly from this program as would others with this handicap.

Thank you for your attention to this matter.
Gail Bruso
[redacted]

[redacted]

From: [redacted]
Sent: Friday, April 19, 2002 5:17 AM
To: [redacted]
Subject: Autism Testimony

Dear Sir or Madam:

I have an autistic son named Cristien. I would like an opportunity to tell you what has happened in New Hampshire. The legal/justice system does not recognognize he is disabled. Even with guardianship, they did not give him his rights as they totally ignored the petition and had him sign giving up the right to a trial by jury. They found my son guilty of unauthorized taking in our own house and prosecuted him. My son spent 9 months in jail already. I gave the powers of Guardianship to Office of Public Guardians and they didn't have services in place, nor did they see to his needs. For 4 months my son lived on the streets. He didn't go see his probation officer and for the last 60 days my son has been in jail for not seeing his probation officer in violation of probation. My son is not indepdent enough to take care of himself. For 4 months he had no food, clothing or shelter. This is awful and I wanted someone to know.

First, My son has a hernia and medical attention is not on their priority list for him as he is very tolerant to pain and not rolling on the floor in pain.

Second, My son needs services in place. One hour a week of mental health services is not enough for someone who can't be indepdent. Thats over 133 hours that he needs to act indepdently. We have designed a service plan but I need to get Area Agency, and mental health to give him services and training he needs to be indepdent. Area Agency said he is not mentally retarded. But they need to provide services as the developmental disability is in the way, and he needs a designed program.

Third, The legal system needs to acknowledge the Guardianship orders. If my son gets Social Security and APTD (aid to the permanently and totally disabled) doesn't that prove in itself he is disabled enough to need support? He has a Guardian and these papers shouldn't stop on the steps of court. They would not talk to me, they should of included me in the decision making process as I was my sons voice. How can we change this for others?

This young man needs training in social/pragmatic skills, daily living skills, vocational, and he needs a case manager to see that all his needs are met. I need somone knowlegeable in this area of disability and to advocate for him. I need your help to get such a person on a team. I don't want my son in jail because it provides a roof over his head, 3 meals a day, a structured routine and no physical contact.

Thank you for taking the time to read this.
Respectfully submitted,
Michael and Doreen Dykeman
[redacted]

[redacted]

From: [redacted]
Sent: Thursday, April 18, 2002 12:10 PM
To: [redacted]
Subject: autism testimony

Dear Beth,
I am a mother of a 7 year old autistic child. I had him in public school from age 3 to age 6. Although the school district had an "autism specialist" and claimed to do a variety of education methods they refused to do the only curriculum proven to help children with autism. Applied Behavior Analysis and the newer version called Applied Verbal Behavior were what were recommended to us on a trip to Johns Hopkins hospital and the Kennedy Krieger Institute. Despite our training of the public school teachers and all of our doctor's recommendations the school refused to do any ABA or AVB claiming it was not possible for them to do. Rather than fight the school district in court I home schooled my child AFTER public school each day and on weekends until he was 6 and an opening came up in a private ABA school in Austin. Matthew has made huge gains both with his behavior and in his communication with this AVB method. We met his IEP goals in 3 months that the public school had been working on for 2 years! This private school that uses the AVB method and a one to one ratio costs our family 25k a year. So as you can imagine very few people can afford this school or even to do an in home program at $25 an hour with a 25 hour minimum a week that is recommended. The children in Texas are being denied this educational model not because it is inappropriate but because the school would rather hire untrained aides to baby-sit our kids. Since the aides and teachers lack any knowledge of how to control autistic behavior we are creating a huge society of autistic adults who will never be able to function in our world or hold a job. Yes, training and intense teaching are difficult and expensive, but you don't have enough institutions to hold all of us that are coming. Fix the education system now or pay later it's as simple as that. I had cause to sue my school district, and in retrospect I may have been able to make more of a difference for the kids who cannot afford private school. I am hopeful that with the progress that is being made with autistic children using AVB and ABA and intense teaching that the proof will be in the success of our children. The school districts will no longer be able to claim that ABA and AVB are not effective teaching models. Autism is skyrocketing are you ready?
Yours truly, Trina Sherman Round Rock Texas 512-255-7989

-----Original Message-----
From: [redacted]
Sent: Thursday, April 18, 2002 8:41 AM
To: [redacted]
Subject: [Texas-Autism-Advocacy] Today's IDEA Congressional Hearings..........

*****Please flood the Government office with statements for the hearing record!!!!!
Beth Clay is Congressman Burton's assistant - e-mail her your concerns on special education!!! [redacted]

******

Today's Congressional hearing can be viewed from the Government Reform Committee Website.

http://www.house.gov/reform

The hearing record will remain open for two weeks - until May 3.

Written submissions to the hearing record may be sent via e-mail as a

Word or WordPerfect attachment (or in the body of an e-mail if you
prefer)
to
[redacted] (e-mail is prefered to snail mail and to
faxes)

Please be sure to put "Autism Testimony" as the subject of the e-mail so the testimony is included.

See you at the rally on Sunday!

[redacted]

------------------------ Yahoo! Groups Sponsor ---------------------~-->
Buy Stock for $4
and no minimums.
FREE Money 2002.
http://us.click.yahoo.com/k6cvND/n97DAA/ySSFAA/wzSolB/TM
---~->

TEXAS-AUTISM-ADVOCACY WEBSITE: http://www.angelfire.com/tx5/autismlist

FEAT News Information:
http://www.feat.org/scripts/wa.exe
http://www.feat.org
"Healing Autism: No Finer a Cause on the Planet"

Your use of Yahoo! Groups is subject to
http://docs.yahoo.com/info/terms/